OFFERYNNAU STATUDOL CYMRU

2011 Rhif 704 (Cy.108)

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011

NODYN ESBONIADOL

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

Mae Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011 ("y Rheoliadau") yn gwneud trefniadau newydd ar gyfer hysbysu, ystyried ac ymateb i bryderon a hysbysir gan bersonau mewn perthynas â gwasanaethau a ddarperir gan neu o dan drefniadau gyda'r Gwasanaeth Iechyd Gwladol yng Nghymru.

Diffinnir pryder fel cwyn, hysbysiad o ddigwyddiad sy'n ymwneud â diogelwch claf, neu, ac eithrio mewn perthynas â phryderon a hysbysir ynghylch darparwyr gofal sylfaenol neu ddarparwyr annibynnol, hawliad am ddigolledidiad.

Mae'r Rheoliadau hefyd yn cyflwyno'r cysyniad o "iawn". Maent yn gosod rhwymedigaeth ar gorff GIG Cymru, pan hysbysir ef o bryder sy'n honni bod, neu y gallai fod, niwed wedi ei achosi, i ystyried pa un a oes atebolrwydd cymwys ai peidio.

Mae Rhan 7 o'r Rheoliadau yn cynnwys darpariaethau sy'n rhoi manylion o'r modd y bydd y trefniadau iawn yn gweithredu pan fo corff GIG Cymru yn ymuno mewn trefniadau gyda chorff GIG yn Lloegr, yr Alban neu Ogledd Iwerddon.

Nid yw'r elfennau o'r Rheoliadau sy'n ymwneud ag iawn yn gymwys i ddarparwyr gofal sylfaenol nac i ddarparwyr annibynnol.

Mae'r Rheoliadau'n disodli'r trefniadau presennol ar gyfer gwneud ac ystyried cwynion, a gynhwysir mewn tair set o Gyfarwyddiadau ar wahân. Mae'r

WELSH STATUTORY INSTRUMENTS

2011 No. 704 (W.108)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

EXPLANATORY NOTE

(This note is not part of the Regulations)

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the Regulations") make new arrangements for the notification and consideration of and response to concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales.

A concern is defined as a complaint, a notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation.

The Regulations also introduce the concept of "redress". They place an obligation on a Welsh NHS body to consider, when it is notified of a concern that alleges harm has or may have been caused, whether or not there is a qualifying liability.

Part 7 of the Regulations contains provisions detailing how the redress arrangements will operate when a Welsh NHS body enters into arrangements with an NHS body in England, Scotland or Northern Ireland.

The redress elements of the Regulations do not apply to primary care providers or independent providers.

The Regulations replace the existing arrangements for the making and consideration of complaints which are contained in three separate sets of Directions. The

Rheoliadau'n dirymu'r Cyfarwyddiadau hynny, yn ddarostyngedig i ddarpariaethau trosiannol; ac yn Atodlen 2, gwneir diwygiadau canlyniadol i'r telerau gwasanaethu sy'n berthnasol i ddarparwyr gofal sylfaenol yng Nghymru.

RHAN 1

Cyffredinol

Mae'r Rheoliadau yn gymwys i wasanaethau a ddarperir yn rhan o'r gwasanaeth iechyd yng Nghymru.

Daw Rhannau 1 i 6 ac 8 i 10 o'r Rheoliadau i rym ar 1 Ebrill 2011. Daw Rhan 7 o'r Rheoliadau i rym ar 1 Hydref 2011.

Mae rheoliad 2 yn diffinio termau a ddefnyddir yn y Rheoliadau. Mae'r diffiniadau allweddol yn cynnwys diffiniadau o "cwyn", "pryder", "darparwr gofal sylfaenol", "atebolrwydd cymwys mewn camwedd", "gwasanaethau cymwys" a "corff cyfrifol".

Mae rheoliad 3 yn sefydlu'r egwyddorion cyffredinol y mae'n rhaid eu dilyn wrth drin ac ymchwilio i bryderon o dan y Rheoliadau.

RHAN 2

Dyletswydd i wneud trefniadau ar gyfer trin ac ymchwilio i bryderon

Mae rheoliad 4 yn darparu bod rhaid i gorff cyfrifol wneud trefniadau, yn unol â'r Rheoliadau hyn, ar gyfer trin ac ymchwilio i bryderon.

Mae rheoliad 5 yn darparu bod rhaid cyhoeddi trefniadau ar gyfer trin pryderon, yn unol â darpariaethau'r rheoliad hwnnw.

Mae rheoliad 6 yn gwneud yn ofynnol bod corff cyfrifol yn dynodi person i fod yn gyfrifol am oruchwylio'r modd y mae'r corff yn gweithredu'r trefniadau o dan y Rheoliadau. Mae rheoliad 7 yn darparu bod rhaid dynodi swyddog cyfrifol i ymgymryd â'r cyfrifoldeb am weithredu'r broses o ddydd i ddydd, er mwyn sicrhau y trinnir pryderon mewn modd integredig. Mae rheoliad 8 yn gwneud yn ofynnol bod corff cyfrifol yn dynodi uwch-reolwr ymchwiliadau i oruchwylio'r gwaith o drin ac ystyried pryderon.

Mae rheoliad 9 yn darparu bod rhaid i gorff cyfrifol sicrhau bod ei staff yn cael hyfforddiant priodol i'w galluogi i gydymffurfio â gofynion y Rheoliadau.

Regulations revoke the Directions, subject to transitional provisions, and make, in Schedule 2, consequential amendments to the relevant terms of service for primary care providers in Wales.

PART 1

General

The Regulations apply to services provided as part of the health service in Wales.

Parts 1 to 6 and 8 to 10 of the Regulations come into force on 1 April 2011. Part 7 of the Regulations comes into force on 1 October 2011.

Regulation 2 defines terms used in the Regulations. Key definitions include the definition of "complaint", "concern", "primary care provider", "qualifying liability in tort", "qualifying services" and "responsible body".

Regulation 3 establishes the general principles which must be followed when handling and investigating concerns under the Regulations.

PART 2

Duty to Make Arrangements for the Handling and Investigation of Concerns

Regulation 4 provides that a responsible body must make arrangements, in accordance with these Regulations, for the handling and investigation of concerns.

Regulation 5 provides that arrangements for handling concerns must be published in accordance with the provisions of that regulation.

Regulation 6 stipulates that a responsible body is required to designate a person to be responsible for the oversight of its operation of the arrangements under the Regulations. Regulation 7 provides that a responsible officer must be designated to take responsibility for the day to day operation of the process to ensure concerns are dealt with in an integrated manner. Regulation 8 requires a responsible body to designate a senior investigations manager who will oversee the handling and consideration of concerns.

Regulation 9 provides that a responsible body must ensure that its staff receive appropriate training to enable them to comply with the requirements of the Regulations.

RHAN 3

Natur a chwmpas y trefniadau ar gyfer trin pryderon

Mae rheoliad 10 yn darparu bod rhaid i gorff cyfrifol drin pryderon yn unol â'r trefniadau ar gyfer trin pryderon a bennir yn y Rheoliadau. Mynegir bod rheoliad 10 yn ddarostyngedig i reoliad 14, sy'n pennu pa faterion a phryderon a eithrir rhag eu hystyried o dan y Rheoliadau.

Mae rheoliad 11 yn darparu y caniateir hysbysu pryder mewn ysgrifen, yn electronig neu ar lafar. Os hysbysir pryder ar lafar, rhaid paratoi cofnod ysgrifenedig o'r pryder, a darparu copi o'r cofnod i'r person a hysbysodd y pryder.

Mae rheoliad 12(1) yn pennu pwy gaiff hysbysu pryder o dan y Rheoliadau. Mae rheoliad 12(2) yn darparu y caiff cynrychiolydd hysbysu pryder ar ran person sy'n sydd neu a fu'n cael gwasanaethau, os bu farw'r person hwnnw, os yw'n blentyn, os nad oes galluedd ganddo neu os ydyw, yn syml, wedi gofyn i gynrychiolydd weithredu ar ei ran. Mae rheoliad 12(3) yn ymdrin â hysbysu pryderon gan gynrychiolydd ar ran plentyn. Yn unol â rheoliad 12(4), pan fo plentyn yn hysbysu pryder, rhaid i gorff cyfrifol ddarparu pa bynnag gymorth a fydd yn ofynnol yn rhesymol gan y plentyn er mwyn mynd ymlaen â'r pryder. Mae rheoliadau 12(5) a (6) yn ymdrin ag ystyried pryderon a hysbysir ar ran plant a phersonau sydd â diffyg galluedd pan fo'r corff cyfrifol o'r farn nad yw'r cynrychiolydd a hysbysodd y pryder yn berson addas i weithredu fel cynrychiolydd, neu nad yw'n mynd ymlaen â'r pryder er budd gorau'r plentyn neu'r person sydd â diffyg galluedd. Mae rheoliad 12(7) yn ymdrin â phryderon a hysbysir gan aelod o staff corff cyfrifol, ac yn pennu'r amgylchiadau pan fydd rhaid hysbysu'r claf a'i gynnwys yn yr ymchwiliad i bryderon o'r fath. Mae rheoliad 12(8) yn nodi'r amgylchiadau pan gaiff corff cyfrifol ffurfio barn na ddylid hysbysu a chynnwys y claf yn yr ymchwiliad i bryderon o'r fath.

Mae rheoliad 13 yn pennu'r materion y caniateir hysbysu pryderon yn eu cylch. Caniateir hysbysu pryder: i Fwrdd Iechyd Lleol neu Ymddiriedolaeth Gwasanaeth Iechyd Gwladol sy'n rheoli ysbyty neu sefydliad arall a leolir yn gyfan gwbl neu'n bennaf o fewn Cymru, ynghylch unrhyw fater sy'n gysylltiedig ag arfer ei swyddogaethau; wrth ddarparwr gofal sylfaenol (a gyfyngir gan y diffiniad yn rheoliad 2 i ddarparwyr gofal sylfaenol yng Nghymru sy'n darparu gwasanaethau yn unol â Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006) ynglŷn â darparu gwasanaethau gan y darparwr gofal sylfaenol o dan gontract neu drefniadau gyda chorff GIG Cymru; neu wrth ddarparwr annibynnol yng Nghymru ynglŷn â darparu gwasanaethau gan y darparwr annibynnol o dan drefniadau gyda chorff GIG Cymru. Ar yr amod y bodlonir gofynion rheoliad 18, caiff person hefyd

PART 3

Nature and Scope of the Arrangements for Handling Concerns

Regulation 10 provides that a responsible body must handle concerns in accordance with the arrangements for handling concerns set out in the Regulations. Regulation 10 is expressed to be subject to regulation 14 which sets out which matters and concerns are excluded from consideration under the Regulations.

Regulation 11 provides that a concern may be notified in writing, electronically or verbally. If a concern is notified verbally a written record of the concern must be prepared and a copy provided to the person who notified the concern.

Regulation 12(1) sets out who may notify a concern under the Regulations. Regulation 12(2) provides that a representative may notify a concern on behalf of a person who is receiving or has received services where that person has died, is a child, lacks capacity or has simply requested a representative to act on his or her behalf. Regulation 12(3) deals with the notification of concerns by a representative on behalf of a child. Pursuant to regulation 12(4) a responsible body must provide a child who notifies a concern with such assistance as the child may reasonably require to pursue the concern. Regulations 12(5) and (6) deal with the consideration of concerns notified on behalf of children and persons who lack capacity where the responsible body is of the opinion that the representative who notified the concern is not a suitable person to act as a representative or who is not pursuing the concern in the best interests of the child or person who lacks capacity. Regulation 12(7) deals with concerns that are reported by a member of staff of a responsible body and sets out when a patient must be informed of and involved in the investigation of such concerns. Regulation 12(8) sets out the circumstances in which a responsible body may form the opinion that a patient should not be informed of and involved in the investigation of such concerns.

Regulation 13 sets out the matters in respect of which concerns may be notified. A concern may be notified to: a Local Health Board or a National Health Service Trust managing a hospital or other establishment wholly or mainly in Wales about any matter connected with the exercise of its functions; to a primary care provider (which is defined in regulation 2 to be limited to primary care providers in Wales providing services pursuant to the National Health Service (Wales) Act 2006) about the provision of services by it under a contract or arrangements with a Welsh NHS body; or an independent provider in Wales about the provision of services by it under arrangements with a Welsh NHS body. Provided the requirements of regulation 18 are met, a person may also notify a concern to a Local Health Board about any matter connected with the provision of services by

hysbysu pryder i Fwrdd Iechyd Lleol ynghylch unrhyw fater mewn cysylltiad â darparu gwasanaethau gan ddarparwr gofal sylfaenol o dan gontract neu drefniant gyda'r Bwrdd Iechyd Lleol.

Mae rheoliad 14(1) yn pennu'r materion a phryderon a eithrir o briod faes y trefniadau a wneir o dan y Rheoliadau. Mae rheoliad 14(2) yn darparu bod rhaid i gorff cyfrifol, os yw o'r farn bod y mater neu bryder yn ymwneud â mater neu bryder a eithriwyd felly, hysbysu'r person a hysbysodd y pryder cyn gynted ag y bo'n rhesymol ymarferol, mewn ysgrifen, gan roi'r rheswm dros ei benderfyniad.

Mae rheoliad 15 yn pennu'r terfynau amser ar gyfer hysbysu pryderon o dan y Rheoliadau hyn.

Mae rheoliad 16 yn darparu y caiff y person a hysbysodd y pryder dynnu ei bryder yn ôl ar unrhyw adeg. Caniateir tynnu'n ôl drwy roi hysbysiad mewn ysgrifen, yn electronig neu ar lafar. Mae rheoliad 16(3) yn darparu y caiff corff cyfrifol, hyd yn oed pan fo pryder wedi ei dynnu'n ôl, barhau i ymchwilio i unrhyw faterion a godir gan y pryder, os yw'r corff cyfrifol o'r farn bod angen gwneud hynny.

a primary care provider under a contract or arrangement with the Local Health Board.

Regulation 14(1) sets out the matters and concerns which are excluded from the scope of the arrangements under the Regulations. Regulation 14(2) provides that a responsible body must, as soon as reasonably practicable, notify in writing the person who notified the concern if it is of the opinion that the matter or concern relates to an excluded matter or concern and provide the reason for its decision.

Regulation 15 sets out the time limits for the notification of concerns under the Regulations.

Regulation 16 provides that a concern may be withdrawn at any time by the person who notified the concern. The withdrawal may be notified in writing, electronically or verbally. Regulation 16(3) provides that even if a concern is withdrawn, a responsible body may continue to investigate any issues raised by a concern if it considers that it is necessary to do so.

RHAN 4

Pryderon sy'n ymwneud â chyrff cyfrifol eraill

Mae rheoliad 17 yn ymdrin â phryderon sy'n ymwneud â mwy nag un corff cyfrifol. Mae'n gosod dyletswydd ar gyrff cyfrifol i gydweithredu at y diben o gydgysylltu'r gwaith o drin ac ymchwilio i'r pryderon a hysbysir, a sicrhau bod y person a hysbysodd y pryder yn cael ymateb cydgysylltiedig.

Mae rheoliadau 18, 19, 20 a 21 yn ymdrin â phryderon ynghylch darparwyr gofal sylfaenol a hysbysir i'r Bwrdd Iechyd Lleol y mae'r darparwr gofal sylfaenol sy'n destun y pryder wedi ymuno mewn contract neu drefniant ag ef. Mae rheoliad 19 yn ymdrin â'r camau y mae'n rhaid i Fwrdd Iechyd Lleol eu cymryd pan hysbysir pryder wrtho gan, neu ar ran, person sy'n cael, neu a fu'n cael, gwasanaethau gan ddarparwr gofal sylfaenol. Mae rheoliad 20 yn ymdrin â'r camau y mae'n rhaid i Fwrdd Iechyd Lleol eu cymryd pan hysbysir pryder wrtho gan ddarparwr gofal sylfaenol. Mae rheoliadau 19 a 20 ill dau'n gwneud yn ofynnol bod Bwrdd Iechyd Lleol yn ystyried a yw'n briodol i'r pryder gael ei ystyried gan y Bwrdd, ynteu a fyddai'n fwy priodol iddo gael ei ystyried gan y darparwr gofal sylfaenol sy'n destun y pryder. Mae rheoliad 21 yn ymdrin â hysbysu ynghylch penderfyniad a wnaed gan y Bwrdd Iechyd Lleol o dan reoliad 19 neu 20. Mae'n pennu'r terfyn amser perthnasol ar gyfer gwneud penderfyniad ac yn gosod dyletswydd ar y Bwrdd Iechyd Lleol i roi rheswm am y penderfyniad.

PART 4

Concerns which involve other Responsible Bodies

Regulation 17 deals with concerns involving more than one responsible body. It places a duty on responsible bodies to co-operate for the purposes of co-ordinating the handling and investigation of the concern notified and must ensure that the person who notified the concern receives a co-ordinated response.

Regulations 18, 19, 20 and 21 deal with concerns about primary care providers which are notified to the Local Health Board with whom the primary care provider, who is the subject of the concern, has entered into a contract or arrangement. Regulation 19 deals with the action that a Local Health Board must take when it receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider. Regulation 20 deals with the action that a Local Health Board must take when it receives a concern notified by a primary care provider. Both regulations 19 and 20 require a Local Health Board to consider whether or not it is appropriate for it to consider the concern or whether it is more appropriate for the primary care provider who is the subject of the concern to consider it. Regulation 21 deals with notification by a Local Health Board of the decision made under regulation 19 or 20. It sets out the relevant time limit for making a decision and the duty on the Local Health Board to give a reason for the decision.

RHAN 5

Trin ac ymchwilio i bryderon

Mae rheoliad 22 yn darparu bod rhaid i gorff cyfrifol, oni fydd eithriadau penodedig yn gymwys, gydnabod cael hysbysiad o bryder, ddim hwyrach na dau ddiwrnod gwaith ar ôl ei gael. Rhaid i gorff cyfrifol hefyd gynnig trafod, gyda'r person a hysbysodd y pryder, y materion sy'n ymwneud â'r ymchwiliad i'r pryder a amlinellir yn rheoliad 22(4). Yn unol â rheoliad 22(6) rhaid i gorff cyfrifol anfon copi o'r hysbysiad o bryder at y person sy'n destun y pryder, oni bai bod y corff cyfrifol yn credu y byddai darparu copi, ym marn resymol y corff cyfrifol, yn rhagfarnu'r ystyriaeth gan y corff cyfrifol o'r materion a godir gan y pryder.

Mae rheoliad 23 yn darparu bod rhaid i gorff cyfrifol ymchwilio i'r materion a godir gan hysbysiad o bryder yn y modd sy'n ymddangos fwyaf priodol i'r corff hwnnw. Rhaid iddo roi sylw penodol i'r materion a grybwyllir yn rheoliad 23(1). Mae rheoliad 23(1)(ff) yn darparu, pan fo corff GIG Cymru yn cael hysbysiad o bryder sy'n cynnwys honiad bod, neu y gallai fod, niwed wedi ei achosi, bod rhaid i'r corff hwnnw ystyried y tebygolrwydd o unrhyw atebolrwydd cymwys; y ddyletswydd i ystyried iawn yn unol â darpariaethau rheoliad 25; a phan fo'n briodol, ystyried y gofynion ychwanegol a bennir yn Rhan 6.

Mae rheoliad 24 yn pennu'r gofynion o ran ymateb i ymchwiliad o dan reoliad 23. **Nid** yw rheoliad 24 yn gymwys pan fo corff GIG Cymru o'r farn bod, neu y gall fod, atebolrwydd cymwys. Yn yr amgylchiadau hynny, rhaid paratoi adroddiad interim o dan reoliad 26. Ym mhob amgylchiad arall, rhaid paratoi ymateb o dan reoliad 24. Mae rheoliad 24(1) yn rhagnodi'r hyn y mae'n rhaid ei gynnwys mewn ymateb o dan reoliad 24. Mae rheoliad 24(3), (4) a (5) yn rhagnodi'r terfynau amser ar gyfer anfon ymateb at y person a hysbysodd y pryder. Mae rheoliad 24(3) yn gosod dyletswydd ar gyrff GIG Cymru i ddarparu rhesymau os penderfynant, mewn perthynas â hysbysiad o bryder a oedd yn honni bod neu y gallai fod niwed wedi ei achosi, nad oes atebolrwydd cymwys ac nad ysgogir y trefniadau ar gyfer iawn yn Rhan 6.

PART 5

Handling and Investigation of Concerns

Regulation 22 provides that unless specified exceptions apply, a responsible body must notify receipt of a concern not later than two working days after receipt. A responsible body must also offer to discuss with the person who notified the concern matters relating to the investigation of the concern outlined in regulation 22(4). Pursuant to regulation 22(6) a responsible body must send a copy of the notification of a concern to the person who is the subject of the concern unless it is of the view that provision of a copy would, in its reasonable opinion, prejudice its consideration of the matters raised by the concern.

Regulation 23 provides that a responsible body must investigate the matters raised by a concern in the manner which appears to that body to be the most appropriate. It must have particular regard to the matters raised in regulation 23(1). Regulation 23(1)(i) provides that where a Welsh NHS body receives notification of a concern which includes an allegation that harm has or may have been caused it must consider the likelihood of any qualifying liability; the duty to consider redress in accordance with the provisions of regulation 25; and, where appropriate, consideration of the additional requirements set out in Part 6.

Regulation 24 sets out the requirements for a response to an investigation under regulation 23. Regulation 24 does **not** apply where a Welsh NHS body considers that there is or there may be a qualifying liability. In those circumstances an interim report under regulation 26 must be produced. In all other circumstances, a response under regulation 24 must be prepared. Regulation 24(1) prescribes the content of a response under regulation 24. Regulation 24(3), (4) and (5) prescribe the timescales for sending a response to the person who notified the concern. Regulation 24(3) places a duty on Welsh NHS bodies to provide reasons if, in relation to a concern that alleges harm has been or may have been caused, they come to the decision that there is no qualifying liability and the redress arrangements in Part 6 will not be triggered.

RHAN 6

Iawn

Nid yw'r ddyletswydd i ystyried iawn o dan Ran 6 ond yn gymwys i gyrff GIG Cymru a ddiffinnir yn rheoliad 2 fel Byrddau Iechyd Lleol ac Ymddiriedolaethau'r Gwasanaeth Iechyd Gwladol sy'n

PART 6

Redress

The duty to consider redress under Part 6 only applies to Welsh NHS bodies, which are defined in regulation 2 as Local Health Boards and National Health Service Trusts managing a hospital or other

rheoli ysbyty neu sefydliad arall neu gyfleuster arall sydd yn gyfan gwbl neu yn bennaf yng Nghymru. Nid yw'n gymwys i ddarparwyr gofal sylfaenol na darparwyr annibynnol.

Mae rheoliad 25 yn darparu bod rhaid i gorff GIG Cymru, os yw'n penderfynu, wrth gynnal ymchwiliad yn unol â rheoliad 23, bod neu y gallai fod atebolrwydd cymwys, benderfynu pa un a ddylid cynnig iawn i'r claf ai peidio. Mae rheoliad 25(2) yn gwneud yn eglur y caiff corff GIG Cymru wneud cynnig o iawn os cadarnheir bod atebolrwydd cymwys.

Mae rheoliad 26 yn darparu bod rhaid i gorff GIG Cymru sydd o'r farn, wrth gynnal ymchwiliad o dan reoliad 23, bod neu y gallai fod atebolrwydd cymwys, baratoi adroddiad interim. Mae rheoliad 26(1) yn rhagnodi'r hyn y mae'n rhaid ei gynnwys yn yr adroddiad interim. Mae rheoliad 26(2) (3) a (4) yn pennu'r terfynau amser ar gyfer anfon yr adroddiad interim at y person a hysbysodd y pryder. Mae rheoliad 26(5) a (6) yn rhagnodi'r terfyn amser ar gyfer anfon copi o'r adroddiad ar yr ymchwiliad, y cyfeirir ato yn rheoliad 31, at y person a hysbysodd y pryder neu at ei gynrychiolydd cyfreithiol.

Mae rheoliad 27 yn pennu'r ffurfiau o iawn a ganiateir o dan y Rheoliadau.

Mae rheoliad 28 yn darparu nad oes iawn ar gael mewn perthynas ag atebolrwydd sydd, neu a fu, yn destun achos sifil, ac os cychwynnir achos sifil yn ystod yr ystyriaeth o iawn gan gorff GIG Cymru, rhaid terfynu'r ystyriaeth o iawn gan y corff GIG Cymru, a rhaid hysbysu'r person a hysbysodd y pryder o hynny.

Mae rheoliad 29 yn pennu terfyn o £25,000 ar gyfer yr elfen o ddigolllediad ariannol yn yr iawn. Mae hyn ar gyfer iawndal arbennig a chyffredinol. Mae rheoliad 29(2) yn darparu bod rhaid peidio â chynnig iawn yn unol â'r Rheoliadau os daw i'r amlwg, ar ôl ymchwilio, bod y cwantwm ariannol yn yr hawliad yn fwy na £25,000. Fodd bynnag, mae rheoliad 29(3) yn darparu, os eir dros ben y terfyn ariannol, y caiff y corff GIG Cymru ystyried gwneud cynnig o setliad y tu allan i ddarpariaethau'r Rheoliadau hyn. Mae'r rheoliad yn darparu y cyfrifir gwerth unrhyw ddigolledlad ar sail cyfraith gwlad. Mae pŵer hefyd gan Weinidogion Cymru i ddyroddi tariff digolledu.

Mae rheoliad 30 yn ymdrin ag atal y cyfnodau cyfyngiad perthnasol yn ystod y cyfnod pan fo atebolrwydd yn destun cais am iawn o dan Ran 6 o'r Rheoliadau.

Mae rheoliad 31 yn darparu bod rhaid cofnodi canfyddiadau ymchwiliad i bryder mewn adroddiad ar yr ymchwiliad. Mae rheoliad 31(2) yn pennu'r hyn y mae'n rhaid ei gynnwys yn adroddiad yr ymchwiliad. Mae rheoliad 31(3) yn darparu bod rhaid i gorff GIG Cymru, ac eithrio pan fo darpariaethau rheoliad 31(4) yn gymwys, ddarparu copi o adroddiad yr ymchwiliad

establishment or facility wholly or mainly in Wales. It does not apply to primary care providers or independent providers.

Regulation 25 provides that where a Welsh NHS body determines during the course of an investigation in accordance with regulation 23 that a qualifying liability exists or may exist, it must determine whether or not an offer of redress should be made to the patient. Regulation 25(2) makes it clear that an offer of redress may be made by a Welsh NHS body where it is established that there is a qualifying liability.

Regulation 26 states that where a Welsh NHS body is of the opinion, following an investigation under regulation 23, that there is or there may be a qualifying liability it must produce an interim report. Regulation 26(1) prescribes the content of the interim report. Regulation 26(2), (3) and (4) set out the timescales for sending the interim report to the person who notified the concern. Regulation 26(5) and (6) prescribe the timescale for sending the person who notified the concern, or his or her legal representative, a copy of the investigation report referred to in regulation 31.

Regulation 27 sets out the form that redress may take under the Regulations.

Regulation 28 provides that redress is not available in relation to a liability that is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress must stop and the person who notified the concern must be so advised.

Regulation 29 sets the limit for the financial compensation element of redress at £25,000. This is for special and general damages. Regulation 29(2) provides that if, on investigation, it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Regulations, must not be offered. However, regulation 29(3) provides that if the financial limit will be exceeded, a Welsh NHS body may give consideration to making an offer of settlement outside the provisions of these Regulations. The regulation provides that the value of any compensation awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue a compensation tariff.

Regulation 30 deals with suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 6 of the Regulations.

Regulation 31 provides that the findings of an investigation of a concern must be recorded in an investigation report. Regulation 31(2) sets out what must be included in an investigation report. Regulation 31(3) provides that unless the provisions of regulation 31(4) apply, a Welsh NHS body must provide the person who is seeking redress under Part 6 of the

i'r person sy'n ceisio iawn o dan Ran 6 o'r Rheoliadau, neu i'w gynrychiolydd cyfreithiol.

Mae rheoliad 32 yn darparu bod rhaid i gorff GIG Cymru, pan fo wedi penderfynu bod, neu y gall fod atebolrwydd cymwys, sicrhau bod cyngor cyfreithiol ar gael yn unol â darpariaethau'r rheoliad hwn. Rhaid iddo hefyd sicrhau, pan fo angen cyfarwyddo arbenigwyr meddygol, y cyfarwyddir hwy ar y cyd gan y corff GIG Cymru a'r person a hysbysodd y pryder. Mae rheoliad 32(2) yn darparu bod rhaid ceisio unrhyw gyngor cyfreithiol gan y ffyrmiau cyfreithwyr hynny, yn unig, sydd ag o leiaf un partner sy'n aelod o naill ai Panel Esgeuluster Clinigol Cymdeithas y Cyfreithwyr neu Banel Esgeuluster Clinigol Gweithredu yn erbyn Damweiniau Meddygol. Mae rheoliad 32(3) yn pennu'r materion y mae'n rhaid rhoi cyngor cyfreithiol ar gael mewn perthynas â hwy yn ddi-dâl i'r person a hysbysodd y pryder. Mae rheoliad 32(4) yn darparu bod rhaid i gost y cyfryw gyngor cyfreithiol a chostau sy'n codi o gyfarwyddo arbenigwyr meddygol gael eu dwyn yn gyfan gwbl gan y corff GIG Cymru.

Mae rheoliad 33 yn rhagnodi'r terfynau amser sy'n gymwys o ran: gwneud cynigion o iawn; hysbysu ynghylch penderfyniadau i beidio â chynnig iawn; ystyried cynigion a gwrthodiadau i wneud cynigion, ac estyniadau i'r cyfryw derfynau amser. Mae rheoliad 33(d) yn darparu y bydd unrhyw setliad a gynigir ar ffurf cytundeb ffurfiol, ac y bydd rhaid i'r cytundeb gynnwys ildiad o unrhyw hawl i ddwyn achos sifil mewn perthynas â'r atebolrwydd cymwys y mae'r setliad yn ymwneud ag ef. Mae rheoliad 33(e) yn darparu, pan fo setliad yn ddarostyngedig i gymeradwyaeth llys, bod rhaid i'r corff GIG Cymru dalu'r costau cyfreithiol rhesymol sy'n gysylltiedig â chael y gymeradwyaeth honno.

Regulations, or his or her legal representative, with a copy of the investigation report.

Regulation 32 provides that where a Welsh NHS body has determined that a qualifying liability exists or may exist it must ensure that legal advice is available, in accordance with the provisions of this regulation. It must also ensure that if medical experts need to be instructed, they are instructed jointly by the Welsh NHS body and the person who notified the concern. Regulation 32(2) provides that legal advice can only be sought from firms of solicitors who have at least one partner or employee who is a member of either the Law Society Clinical Negligence Panel or the Action Against Medical Accidents Clinical Negligence Panel. Regulation 32(3) sets out the matters in respect of which legal advice, without charge to the person who notified the concern, must be made available. Regulation 32(4) provides that the cost of such legal advice and costs arising from the instruction of medical experts must be borne in their entirety by the Welsh NHS body.

Regulation 33 prescribes the time limits that apply to the making of offers of redress; the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 33(e) provides that any offer of settlement will be by way of formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates. Regulation 33(g) provides that where a settlement is subject to court approval, the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

RHAN 7

Gofynion ar gyrff GIG, ac eithrio cyrff GIG Cymru, i ystyried iawn, a'r weithdrefn sydd i'w dilyn gan gorff GIG Cymru pan yw'n cael hysbysiad o bryder yn unol â darpariaethau'r Rhan hon.

Mae Rhan 7 yn ymdrin â'r modd y mae'r iawn i'w ddarparu pan fo cyrff GIG Cymru yn ymuno mewn trefniadau gyda chyrff GIG yn Lloegr, yr Alban neu Ogledd Iwerddon. Mae darparwyr gofal sylfaenol a darparwyr annibynnol wedi eu heithrio o'r trefniadau o dan Ran 7.

Mae rheoliad 34 yn diffinio'r termau a ddefnyddir yn Rhan 7.

Mae rheoliad 35 yn gosod dyletswydd ar "gorff GIG Lloegr" (term a ddiffinnir yn rheoliad 34), sy'n cael hysbysiad o bryder neu gŵyn ynghylch gwasanaeth a ddarparwyd ganddo neu a drefnodd i'w ddarparu o dan drefniadau gyda chorff GIG Cymru, i ystyried, wrth

PART 7

Requirements for NHS Bodies, other than Welsh NHS Bodies, to Consider Redress and Procedure to be Followed by a Welsh NHS Body when it Receives Notification of a Concern in Accordance with the Provisions of this Part.

Part 7 deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with NHS bodies in England, Scotland or Northern Ireland. Primary care providers and independent providers are excluded from the scope of the arrangements under Part 7.

Regulation 34 defines terms that are used in Part 7.

Regulation 35 places a duty on an "English NHS body", which is a term defined in regulation 34, that receives notification of a concern or a complaint about a service which it has provided or arranged for the provision of under arrangements with a Welsh NHS

ymchwilio i'r pryder neu'r gŵyn, a oes neu a allai fod atebolrwydd cymwys.

body, to consider, when investigating the complaint or concern, whether or not a qualifying liability exists or may exist.

Mae rheoliad 36(1) yn darparu os yw corff GIG Lloegr yn dod i'r casgliad bod, neu y gallai fod atebolrwydd o'r fath, rhaid iddo gymryd y camau a amlinellir yn rheoliad 36(2).

Regulation 36(1) provides that if an English NHS body concludes that such a liability exists or may exist it must take the steps outlined in regulation 36(2).

Mae rheoliad 36(2) yn gosod dyletswydd ar gorff GIG Lloegr i hysbysu'r corff GIG Cymru, yr ymunodd mewn trefniant gydag ef, os yw o'r farn bod atebolrwydd cymwys naill ai'n bodoli, neu y gallai fodoli. Rhaid iddo wedyn, ar ôl cael y caniatadau priodol gan y claf neu, mewn rhai amgylchiadau, gan gynrychiolydd y claf, ddarparu i'r corff GIG Cymru yr wybodaeth a'r dogfennau a amlinellir ym mharagraffau (a) i (dd).

Regulation 36(2) places a duty on an English NHS body to notify the Welsh NHS body with whom it has entered into an arrangement if it is of the view that a qualifying liability exists or may exist. It must then, after obtaining the appropriate consents from the patient or, in certain cases his or her representative, provide the Welsh NHS body with the information and documentation outlined at paragraphs (a) to (f).

Mae rheoliad 37 yn rhagnodi'r camau y mae'n rhaid i gorff GIG Cymru eu cymryd ar ôl cael hysbysiad yn unol â rheoliad 36 gan gorff GIG Lloegr.

Regulation 37 prescribes the action that a Welsh NHS body must take when it receives notification from an English NHS body in accordance with regulation 36.

Mae rheoliad 38 yn rhagnodi'r camau y mae'n rhaid i gorff GIG Cymru eu cymryd os yw'n cael hysbysiad gan gorff GIG yr Alban neu gorff GIG Gogledd Iwerddon i'r perwyl bod, neu y gallai fod, atebolrwydd cymwys.

Regulation 38 prescribes the action that a Welsh NHS body is required to take if it receives a notification from a Scottish NHS body or a Northern Irish NHS body that there is, or there may be, a qualifying liability.

Mae rheoliad 39 yn gosod dyletswydd ar gyrff GIG Cymru i gynnal ymchwiliad ar ôl cael hysbysiad gan gorff GIG Lloegr, corff GIG yr Alban neu gorff GIG Gogledd Iwerddon. Mae rheoliad 39(2) yn gosod dyletswydd i gydweithio ar gyrff GIG Cymru a Chyrff GIG Lloegr.

Regulation 39 places a duty on Welsh NHS bodies to conduct an investigation on receipt of a notification from an English NHS body, a Scottish NHS body or a Northern Irish NHS body. Regulation 39(2) places a duty of co-operation on Welsh NHS bodies and English NHS bodies.

Mae rheoliad 40 yn darparu bod rhaid i gorff GIG Cymru baratoi adroddiad interim, os yw o'r farn, ar ôl cynnal ymchwiliad yn unol â rheoliad 39, bod neu y gallai fod atebolrwydd cymwys. Mae rheoliad 40(1) yn rhagnodi'r hyn y mae'n rhaid ei gynnwys yn yr adroddiad. Mae rheoliad 40(3) a (4) yn pennu'r terfyn amser ar gyfer anfon yr adroddiad interim at y person a hysbysodd y pryder. Mae rheoliad 40(4) yn rhagnodi'r terfyn amser ar gyfer anfon copi o'r adroddiad ar yr ymchwiliad, y cyfeirir ato yn rheoliad 46, at y person a hysbysodd y pryder.

Regulation 40 provides that if after conducting an investigation in accordance with regulation 39 a Welsh NHS body is of the opinion that there is or there may be a qualifying liability, the Welsh NHS body must produce an interim report. Regulation 40(1) prescribes the content of the report. Regulation 40(3) and (4) prescribe the timescales for sending the interim report to the person who notified the concern. Regulation 40(4) prescribes the timescale for sending the person who notified the concern a copy of the investigation report referred to in regulation 46.

Mae rheoliad 41 yn rhagnodi'r camau y mae'n rhaid i gorff GIG Cymru eu cymryd pan yw'n penderfynu, yn dilyn ymchwiliad yn unol â darpariaethau rheoliad 39, nad yw pryder, a hysbyswyd gan gorff GIG Lloegr yn unol â rheoliad 36 neu gan gorff GIG yr Alban neu gorff GIG Gogledd Iwerddon (yn unol â darpariaethau mewn contract comisiynu) yn cynnwys atebolrwydd cymwys.

Regulation 41 prescribes the action that a Welsh NHS body must take when, following an investigation in accordance with the provisions of regulation 39, it decides that a concern notified by an English NHS body in accordance with regulation 36 or a Scottish NHS body or Northern Irish NHS body (in accordance with provisions in a commissioning contract) does not involve a qualifying liability.

Mae rheoliad 42 yn pennu'r ffurf o iawn a ganiateir o dan Ran 7 o'r Rheoliadau.

Regulation 42 sets out the form that redress may take under Part 7 of the Regulations.

Mae rheoliad 43 yn darparu nad oes iawn ar gael mewn perthynas ag atebolrwydd sydd, neu a fu, yn destun achos sifil, ac os cychwynnir achos sifil yn ystod yr ystyriaeth o iawn gan gorff GIG Cymru, rhaid terfynu'r ystyriaeth o iawn gan y corff GIG Cymru, a

Regulation 43 provides that redress is not available in relation to a liability that is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of

rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder o hynny, yn ogystal â'r corff GIG Lloegr, corff GIG yr Alban neu'r corff GIG Gogledd Iwerddon fel y bo'n briodol.

Mae rheoliad 44 yn pennu terfyn o £25,000 ar gyfer yr elfen ariannol yn yr iawn. Mae hyn ar gyfer iawndal arbennig a chyffredinol. Mae rheoliad 44(2) yn darparu bod rhaid peidio â chynnig iawn yn unol â'r Rheoliadau os tybir, ar ôl ymchwilio, bod y cwantwm ariannol yn yr hawliad yn fwy na £25,000. Mae'r rheoliad yn darparu y cyfrifir gwerth unrhyw ddigolledied ar sail cyfraith gwlad. Mae pŵer hefyd gan Weinidogion Cymru i ddyroddi tariff digolledu.

Mae rheoliad 45 yn ymdrin ag atal y cyfnodau cyfyngiad perthnasol yn ystod y cyfnod pan fo atebolrwydd yn destun cais am iawn o dan Ran 7 o'r Rheoliadau.

Mae rheoliad 46 yn darparu bod rhaid cofnodi canfyddiadau ymchwiliad i bryder mewn adroddiad ar yr ymchwiliad. Mae rheoliad 46(2) yn pennu'r hyn y mae'n rhaid ei gynnwys yn adroddiad yr ymchwiliad. Mae rheoliad 46(3) yn darparu bod rhaid i gorff GIG Cymru, ac eithrio pan fo darpariaethau rheoliad 46(4) yn gymwys, ddarparu copi o adroddiad yr ymchwiliad i'r person sy'n ceisio iawn o dan Ran 7 o'r Rheoliadau, neu i'w gynrychiolydd cyfreithiol.

Mae rheoliad 47 yn ailadrodd y darpariaethau yn rheoliad 32, ac eithrio bod rheoliad 47(4) yn cyfeirio at y ffaith y gall fod hawliau gan gorff GIG Cymru i adennill cost unrhyw wariant mewn perthynas ag iawn oddi ar gorff GIG Lloegr.

Mae rheoliad 48 yn rhagnodi'r terfynau amser sy'n gymwys o ran gwneud cynigion o iawn; hysbysu ynghylch penderfyniadau i beidio â chynnig iawn; ystyried cynigion a gwrthodiadau i wneud cynigion, ac estyniadau i'r cyfryw derfynau amser. Mae rheoliad 48(d) yn darparu y bydd unrhyw setliad a gynigir ar ffurf cytundeb ffurfiol, ac y bydd rhaid i'r cytundeb gynnwys ildiad o unrhyw hawl i ddwyn achos sifil mewn perthynas â'r atebolrwydd cymwys y mae'r setliad yn ymwneud ag ef. Mae rheoliad 48(e) yn darparu, pan fo setliad yn ddarostyngedig i gymeradwyaeth llys, bod rhaid i'r corff GIG Cymru dalu'r costau cyfreithiol rhesymol sy'n gysylltiedig â chael y gymeradwyaeth honno.

redress must stop and the Welsh NHS body must notify the person who notified the concern and the English NHS body, Scottish NHS body or Northern Irish NHS body as appropriate.

Regulation 44 sets the limit for the financial element of redress at £25,000. This is for special and general damages. Regulation 44(2) provides that if, on investigation, it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Regulations, must not be offered. The regulation provides that the compensation awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue, a compensation tariff.

Regulation 45 deals with the suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 7 of the Regulations.

Regulation 46 provides that the findings of an investigation of a concern must be recorded in an investigation report. Regulation 46(2) sets out what must be included in an investigation report. Regulation 46(3) provides that unless the provisions of regulation 46(4) apply, a Welsh NHS body must provide the person who is seeking redress under Part 7 of the Regulations, or his or her legal representative, with a copy of the investigation report.

Regulation 47 replicates the provisions in regulation 32 save that regulation 47(4) makes reference to the fact that a Welsh NHS body may have rights to recover the cost of any expenditure related to redress from an English NHS body.

Regulation 48 prescribes the time limits that apply to the making of offers of redress; the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 48(e) provides that any offer of settlement will be by way of formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates. Regulation 48(g) provides that where a settlement is subject to court approval the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

RHAN 8

Dysgu o'r pryderon

Mae rheoliad 49 yn darparu bod rhaid i bob corff cyfrifol sicrhau bod ganddo brosesau wedi eu sefydlu, a fydd yn sicrhau bod unrhyw ddiffygion a ganfyddir yng ngweithrediadau'r corff neu ei ddarpariaeth o wasanaethau, wrth ymchwilio i bryder o dan y Rheoliadau hyn, yn ysgogi gweithredu a monitro.

PART 8

Learning from concerns

Regulation 49 provides that each responsible body must ensure that it has processes in place to ensure that any deficiencies in its actions or service provision that are identified as part of an investigation of a concern in accordance with these Regulations are acted upon and monitored.

RHAN 9

Monitro'r broses

Mae rheoliad 50 yn rhagnodi'r materion y mae'n rhaid i gorff cyfrifol gadw cofnod ohonynt er mwyn monitro gweithrediad y trefniadau ar gyfer ymdrin â phryderon o dan y Rheoliadau.

Mae rheoliad 51 yn darparu bod rhaid i gorff cyfrifol baratoi adroddiad blynyddol. Mae rheoliad 51(1) yn rhagnodi'r materion y mae'n rhaid eu cynnwys yn yr adroddiad blynyddol. Mae rheoliad 51(2) a (3) gyda'i gilydd yn darparu bod rhaid i ddarparwr annibynnol, darparwr gofal sylfaenol, neu Ymddiriedolaeth GIG sy'n rheoli ysbyty neu sefydliad arall a leolir yn gyfan gwbl neu'n bennaf o fewn Cymru, os yw'n cytuno i ddarparu gwasanaethau o dan drefniant gyda Bwrdd Iechyd Lleol, anfon copi o'i adroddiad blynyddol at y Bwrdd Iechyd Lleol hwnnw.

PART 9

Monitoring the Process

Regulation 50 prescribes the matters a responsible body must keep a record of in order to monitor the operation of the arrangements for dealing with concerns under the Regulations.

Regulation 51 provides that a responsible body must prepare an annual report. Regulation 51(1) prescribes the content of the annual report. Regulation 51(2) and (3) together provide that an independent provider, a primary care provider or a NHS Trust managing a hospital or other establishment wholly or mainly in Wales must if it agrees to provide services under an arrangement with a Local Health Board, send a copy of its annual report to that Local Health Board.

RHAN 10

Darpariaethau trosiannol a chanlyniadol a dirymiadau

Mae rheoliad 52 yn cynnwys darpariaethau trosiannol.

Mae rheoliad 53 yn dirymu'r Cyfarwyddiadau a bennir ym mharagraffau (a) i (c).

Mae rheoliad 54 yn rhoi effaith i Atodlen 2.

PART 10

Transitional and Consequential Provisions and Revocations

Regulation 52 contains transitional provisions.

Regulation 53 revokes the Directions specified in paragraphs (a) to (c).

Regulation 54 gives effect to Schedule 2.

OFFERYNNAU STATUDOL CYMRU

2011 Rhif 704 (Cy.108)

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011

Gwnaed *8 Mawrth 2011*

Yn dod i rym yn unol â darpariaethau rheoliad 1(2)

TREFN Y RHEOLIADAU

RHAN 1

CYFFREDINOL

1. Enwi, cychwyn a chymhwyso.
2. Dehongli.
3. Egwyddorion cyffredinol ar gyfer trin ac ymchwilio i bryderon.

RHAN 2

DYLETSWYDD I WNEUD TREFNIADAU AR GYFER TRIN AC YMCHWILIO I BRYDERON

4. Dyletswydd i wneud trefniadau.
5. Y trefniadau i'w cyhoeddi.
6. Goruchwyliaeth strategol o'r trefniadau.
7. Y swyddog cyfrifol.
8. Yr uwch-reolwr ymchwiliadau.
9. Gwybodaeth a hyfforddiant i'r staff.

RHAN 3

NATUR A CHWMPAS Y TREFNIADAU AR GYFER TRIN PRYDERON

10. Gofyniad i ystyried pryderon.
11. Hysbysu pryderon.
12. Personau y caniateir iddynt hysbysu pryderon.
13. Materion y caniateir hysbysu pryderon yn eu cylch.
14. Materion a phryderon a eithrir rhag eu hystyried o dan y trefniadau.

WELSH STATUTORY INSTRUMENTS

2011 No. 704 (W.108)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

Made *8 March 2011*

Coming into force in accordance with the provisions of regulation 1(2)

ARRANGEMENT OF REGULATIONS

PART 1

GENERAL

1. Title, commencement and application.
2. Interpretation.
3. General principles for the handling and investigation of concerns.

PART 2

DUTY TO MAKE ARRANGEMENTS FOR THE HANDLING AND INVESTIGATION OF CONCERNS

4. Duty to make arrangements.
5. Arrangements to be published.
6. Strategic oversight of the arrangements.
7. Responsible officer.
8. Senior investigations manager.
9. Information and training for staff.

PART 3

NATURE AND SCOPE OF THE ARRRANGEMENTS FOR HANDLING CONCERNS

10. Requirement to consider concerns.
11. Notification of concerns.
12. Persons who may notify concerns.
13. Matters about which concerns may be notified.
14. Matters and concerns excluded from consideration under the arrangements.

15. Terfyn amser ar gyfer hysbysu pryderon.

16. Tynnu pryderon yn ôl.

RHAN 4

PRYDERON SY'N YMWNEUD Â CHYRFF CYFRIFOL ERAILL

17. Pryderon sy'n ymwneud â mwy nag un corff cyfrifol.

18. Pryderon sy'n ymwneud â darparwyr gofal sylfaenol.

19. Camau sydd i'w cymryd pan hysbysir pryder i Fwrdd Iechyd Lleol ynghylch gwasanaethau a ddarperir gan ddarparwr gofal sylfaenol.

20. Camau sydd i'w cymryd pan hysbysir pryder i Fwrdd Iechyd Lleol gan ddarparwr gofal sylfaenol.

21. Hysbysu ynghylch penderfyniadau a wneir gan Fwrdd Iechyd Lleol yn unol â rheoliadau 19 a 20.

RHAN 5

TRIN AC YMCHWILIO I BRYDERON

22. Y weithdrefn cyn ymchwilio.

23. Ymchwilio i bryderon.

24. Ymateb.

RHAN 6

IAWN

25. Dyletswydd i ystyried iawn.

26. Ymateb i ymchwiliad o dan reoliad 23 pan benderfynir bod, neu y gall fod, atebolrwydd cymwys.

27. Ffurf o iawn.

28. Argaeledd iawn.

29. Iawn – digollediad ariannol.

30. Atal dros dro gyfnod y cyfyngiad.

31. Adroddiad yr ymchwiliad.

32. Cyngor cyfreithiol a chyfarwyddo arbenigwyr meddygol.

33. Iawn – hysbysu ynghylch penderfyniad.

15. Time limit for notification of concerns.

16. Withdrawal of concerns.

PART 4

CONCERNS WHICH INVOLVE OTHER RESPONSIBLE BODIES

17. Concerns involving more than one responsible body.

18. Concerns involving primary care providers.

19. Action to be taken where a Local Health Board receives notification of a concern about services provided by a primary care provider.

20. Action to be taken where a Local Health Board receives notification of a concern from a primary care provider.

21. Communication of decisions made by a Local Health Board in accordance with regulations 19 and 20.

PART 5

HANDLING AND INVESTIGATION OF CONCERNS

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23. Investigation of concerns.

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PART 6

REDRESS

25. Duty to consider redress.

26. Response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability.

27. Form of redress.

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RHAN 7

GOFYNIAD AR GYRFF GIG, AC EITHRIO CYRFF GIG CYMRU, I YSTYRIED IAWN, A'R WEITHDREFN SYDD I'W DILYN GAN GORFF GIG CYMRU PAN GAIFF HYSBYSIAD O BRYDER YN UNOL Â DARPARIAETHAU'R RHAN HON

34. Dehongli'r Rhan hon.
35. Amgylchiadau pan fo rhaid i gorff GIG Lloegr ystyried a allai iawn fod yn gymwys ai peidio.
36. Camau sydd i'w cymryd pan fo corff GIG Lloegr o'r farn bod, neu y gallai fod, atebolrwydd cymwys.
37. Camau sydd i'w cymryd gan gorff GIG Cymru ar ôl cael hysbysiad gan gorff GIG Lloegr yn unol â rheoliad 36.
38. Camau sydd i'w cymryd gan gorff GIG Cymru ar ôl cael hysbysiad gan gorff GIG yr Alban neu gorff GIG Gogledd Iwerddon.
39. Dyletswydd ar gorff GIG Cymru i gynnal ymchwiliad.
40. Ymateb i ymchwiliad o dan reoliad 39 pan fo corff GIG Cymru o'r farn bod, neu y gall fod, atebolrwydd cymwys.
41. Ymateb i ymchwiliad o dan reoliad 39 pan fo corff GIG Cymru yn penderfynu nad oes atebolrwydd cymwys.
42. Ffurf yr iawn.
43. Argaeledd iawn.
44. Iawn – digollediad ariannol.
45. Atal dros dro gyfnod y cyfyngiad.
46. Adroddiad yr ymchwiliad.
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RHAN 8

DYSGU O'R PRYDERON

49. Dysgu o'r pryderon.

RHAN 9

MONITRO'R BROSES

50. Monitro gweithrediad y trefniadau i ymdrin â phryderon.
51. Yr adroddiad blynyddol.

PART 7

REQUIREMENT FOR NHS BODIES, OTHER THAN WELSH NHS BODIES, TO CONSIDER REDRESS AND PROCEDURE TO BE FOLLOWED BY A WELSH NHS BODY WHEN IT RECEIVES NOTIFICATION OF A CONCERN IN ACCORDANCE WITH THE PROVISIONS OF THIS PART

34. Interpretation of this Part.
35. Circumstances in which an English NHS body must consider whether or not redress may apply.
36. Stepss to be taken where an English NHS body considers that a qualifying liability exists or may exist.
37. Action to be taken by a Welsh NHS body on receipt of a notification from an English NHS body in accordance with regulation 36.
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39. Duty of Welsh NHS body to conduct an investigation.
40. Response to an investigation under regulation 39 where a Welsh NHS body is of the opinion that there is, or there may be, a qualifying liability.
41. Response to an investigation under regulation 39 where a Welsh NHS body decides that there is no qualifying liability.
42. Form of redress.
43. Availability of redress.
44. Redress – financial compensation.
45. Suspension of the limitation period.
46. Investigation report.
47. Legal advice and instruction of medical experts.
48. Redress – communication of a decision.

PART 8

LEARNING FROM CONCERNS

49. Learning from concerns.

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MONITORING THE PROCESS

50. Monitoring the operation of arrangements for dealing with concerns.
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DARPARIAETHAU TROSIANNOL A CHANLYNIADOL A DIRYMIADAU

52. Darpariaethau trosiannol.
53. Dirymiadau.
54. Darpariaethau canlyniadol a throsiannol.

YR ATODLENNI

1. Darpariaethau sy'n rhoi'r pwerau a arferwyd wrth wneud y Rheoliadau hyn.
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PART 10

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1. Provisions conferring powers exercised in making these Regulations.
2. Consequential and transitional provisions.

RHAN 1

CYFFREDINOL

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddir gan y darpariaethau a nodir yng ngholofn (1) o Atodlen 1 i'r offeryn hwn, fel y'u diwygiwyd yn benodol gan y darpariaethau a nodir yng ngholofn (2) o'r Atodlen honno, yn gwneud y Rheoliadau canlynol.

Gosodwyd drafft o'r Rheoliadau hyn gerbron Cynulliad Cenedlaethol Cymru ac fe'i cymeradwywyd drwy benderfyniad ganddo yn unol ag adran 11(6) o Fesur Gwneud Iawn am Gamweddau'r GIG (Cymru) 2008.

Enwi, cychwyn a chymhwyso

1.–(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011.

(2) Daw Rhannau 1 i 6 ac 8 i 10 i rym ar 1 Ebrill 2011 a daw Rhan 7 i rym ar 1 Hydref 2011.

(3) Mae'r Rheoliadau hyn yn gymwys i wasanaethau a ddarperir fel rhan o'r gwasanaeth iechyd yng Nghymru.

Dehongli

2.–(1) Yn y Rheoliadau hyn–

ystyr "achos disgyblu" ("*disciplinary proceedings*") yw unrhyw weithdrefn ar gyfer disgyblu cyflogeion a fabwysiedir gan gorff cyfrifol i ddisgyblu cyflogeion;

ystyr "aelod nad yw'n swyddog" ("*non-officer member*") yw aelod o Fwrdd Bwrdd Iechyd Lleol nad yw'n un o gyflogeion y corff hwnnw;

ystyr "aelod sy'n swyddog" ("*officer member*") yw aelod o Fwrdd Bwrdd Iechyd Lleol sy'n un o gyflogeion y corff hwnnw;

ystyr "atebolrwydd cymwys" ("*qualifying liability*") yw atebolrwydd mewn camwedd sy'n ddyledus o ran neu o ganlyniad i anaf personol neu golled sy'n deillio o dor-dyletswydd gofal, neu sy'n gysylltiedig â thor-dyletswydd gofal, a'r ddyletswydd gofal honno yn ddyledus i unrhyw berson mewn cysylltiad â diagnosis o salwch, neu wrth ofalu am unrhyw glaf neu ei drin–

(a) o ganlyniad i unrhyw weithred neu anwaith gan broffesiynolyn gofal iechyd; a

(b) sy'n codi mewn cysylltiad â darparu gwasanaethau cymwys;

ystyr "Bwrdd Iechyd Lleol" ("*Local Health Board*") yw Bwrdd Iechyd Lleol a sefydlwyd yn unol ag adran 11(2) o Ddeddf 2006;

PART 1

GENERAL

The Welsh Ministers, in exercise of the powers conferred by the provisions set out in column (1) of Schedule 1 to this instrument, as amended in particular by the provisions set out in column (2) of that Schedule, make the following Regulations.

A draft of these Regulations was laid before, and approved by resolution of, the National Assembly for Wales in accordance with section 11(6) of the NHS Redress (Wales) Measure 2008.

Title, commencement and application

1.–(1) The title of these Regulations is the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

(2) Parts 1 to 6 and 8 to 10 come into force on 1 April 2011 and Part 7 comes into force on 1 October 2011.

(3) These Regulations apply to services provided as part of the health service in Wales.

Interpretation

2.–(1) In these Regulations–

"the 2006 Act" ("*Deddf 2006*") means the National Health Service (Wales) Act 2006(**1**);

"alternative dispute resolution" ("*dull amgen o ddatrys anghydfod*") means mediation, conciliation or facilitation;

"child" ("*plentyn*") means a person who has not attained the age of eighteen years;

"complaint" ("*cwyn*") means any expression of dissatisfaction;

"concern" ("*pryder*") means any complaint; notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation;

"disciplinary proceedings" ("*achos disgyblu*") means any procedure for disciplining employees adopted by a responsible body for disciplining employees;

"executive director" ("*cyfarwyddwr gweithredol*") means a member of the Board of a National Health Service Trust who is an employee of that body;

"general dental services contractor" ("*contractwr gwasanaethau deintyddol cyffredinol*") means a

(**1**) 2006 c.42.

ystyr "cais am driniaeth i glaf unigol" ("*individual patient treatment request*") yw cais i Fwrdd Iechyd Lleol i gyllido gofal iechyd i glaf unigol sydd y tu allan i'r ystod o wasanaethau a thriniaethau a ddarperir gan y Bwrdd Iechyd Lleol, gan gynnwys y gwasanaethau arbenigol hynny a sicrheir drwy Bwyllgor Gwasanaethau Iechyd Arbenigol Cymru;

ystyr "claf" ("*patient*") yw'r person sy'n cael neu sydd wedi cael gwasanaethau gan gorff cyfrifol;

ystyr "contractwr gwasanaethau deintyddol cyffredinol" ("*general dental services contractor*") yw person sydd wedi ymuno mewn contract gyda Bwrdd Iechyd Lleol i ddarparu gwasanaethau deintyddol cyffredinol yn unol ag adran 57 o Ddeddf 2006;

ystyr "contractwr gwasanaethau meddygol cyffredinol" ("*general medical services contractor*") yw person sydd wedi ymuno mewn contract gyda Bwrdd Iechyd Lleol i ddarparu gwasanaethau meddygol cyffredinol yn unol ag adran 42 o Ddeddf 2006;

ystyr "corff cyfrifol" ("*responsible body*") yw–

(a) corff GIG Cymru;

(b) darparwr gofal sylfaenol; neu

(c) darparwr annibynnol;

ystyr "corff GIG Cymru" ("*Welsh NHS body*") yw–

(a) Bwrdd Iechyd Lleol; neu

(b) Ymddiriedolaeth Gwasanaeth Iechyd Gwladol sy'n rheoli ysbyty neu sefydliad neu gyfleuster arall a leolir yn gyfan gwbl neu'n bennaf yng Nghymru;

ystyr "cwyn" ("*complaint*") yw unrhyw fynegiant o anfodlonrwydd;

ystyr "cyfarwyddwr anweithredol" ("*non-executive director*") yw aelod o Fwrdd Ymddiriedolaeth Gwasanaeth Iechyd Gwladol nad yw'n un o gyflogeion y corff hwnnw;

ystyr "cyfarwyddwr gweithredol" ("*executive director*") yw aelod o Fwrdd Ymddiriedolaeth Gwasanaeth Iechyd Gwladol sy'n un o gyflogeion y corff hwnnw;

ystyr "darparwr annibynnol" ("*independent provider*") yw person neu gorff sydd–

(a) yn darparu gofal iechyd yng Nghymru o dan drefniadau a wnaed gyda chorff GIG Cymru; a

(b) nad yw'n gorff GIG nac yn ddarparwr gofal sylfaenol;

ystyr "darparwr gofal sylfaenol" ("*primary care provider*") yw person neu gorff sydd–

(a) yn gontractwr gwasanaethau meddygol cyffredinol;

(b) yn darparu gwasanaethau meddygol sylfaenol

person who has entered into a contract to provide general dental services with a Local Health Board in accordance with section 57 of the 2006 Act;

"general medical services contractor" ("*contractwr gwasanaethau meddygol cyffredinol*") means a person who has entered into a contract to provide general medical services with a Local Health Board in accordance with section 42 of the 2006 Act;

"health care professional" ("*proffesiynolyn gofal iechyd*") means a member of a profession (whether or not regulated by, or by virtue of, any enactment) which is concerned (wholly or partly) with the physical or mental health of individuals;

"incident concerning patient safety" ("*digwyddiad sy'n ymwneud â diogelwch claf*") means any unexpected or unintended incident which did lead to or could have led to harm for a patient;

"independent provider" ("*darparwr annibynnol*") means a person or body who–

(a) provides health care in Wales under arrangements made with a Welsh NHS body; and

(b) is not an NHS body or a primary care provider;

"individual patient treatment request" ("*cais am driniaeth i glaf unigol*") means a request to a Local Health Board to fund health care for an individual patient that falls outside the range of services and treatments that the Local Health Board provides including those specialist services secured through the Welsh Health Specialist Services Committee;

"Local Health Board" ("*Bwrdd Iechyd Lleol*") means a Local Health Board established in accordance with section 11(2) of the 2006 Act;

"moderate or severe harm" ("*niwed cymedrol neu ddifrifol*") means moderate or severe harm determined in accordance with guidance issued for the purpose of these Regulations by the Welsh Ministers;

"non-executive director" ("*cyfarwyddwr anweithredol*") means a member of the Board of a National Health Service Trust who is not an employee of that body;

"non-officer member" ("*aelod nad yw'n swyddog*") means a member of the Board of a Local Health Board who is not an employee of that body;

"officer member" ("*aelod sy'n swyddog*") means a member of the Board of a Local Health Board who is an employee of that body;

"patient" ("*claf*") means the person who receives or has received services from a responsible body;

"primary care provider" ("*darparwr gofal sylfaenol*") means a person or body who–

yn unol â threfniadau a wnaed o dan adrannau 41(2)(b) a 50 o Ddeddf 2006;

(c) yn gontractwr gwasanaethau deintyddol cyffredinol;

(ch) yn darparu gwasanaethau deintyddol sylfaenol yn unol â threfniadau o dan adran 64 o Ddeddf 2006;

(d) yn darparu gwasanaethau offthalmig cyffredinol yn unol â threfniadau o dan adran 71 o Ddeddf 2006;

(dd) yn darparu gwasanaethau fferyllol yn unol â threfniadau o dan adran 80 o Ddeddf 2006;

(e) yn darparu gwasanaethau fferyllol lleol o dan gynlluniau peilot yn unol ag adran 92 o Ddeddf 2006; neu

(f) yn darparu gwasanaethau fferyllol lleol yn unol â pharagraff 1 o Atodlen 7 i Ddeddf 2006;

ystyr "Deddf 2006" ("*the 2006 Act*") yw Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(**1**);

ystyr "digwyddiad sy'n ymwneud â diogelwch claf" ("*incident concerning patient safety*") yw unrhyw ddigwyddiad annisgwyl neu nas bwriadwyd a arweiniodd, neu a allai fod wedi arwain, at niwed i glaf;

ystyr "diwrnod gwaith" ("*working day*") yw diwrnod ac eithrio dydd Sadwrn neu ddydd Sul, Dydd Nadolig, Gŵyl San Steffan, Dydd Gwener y Groglith, neu ddiwrnod sy'n ŵyl banc yng Nghymru o dan Ddeddf Bancio a Thrafodion Ariannol 1971(**2**);

ystyr "dull amgen o ddatrys anghydfod" ("*alternative dispute resolution*") yw cyfryngu, cymodi neu hwyluso;

ystyr "gweithdrefn gwynion berthnasol" ("*relevant complaints procedure*") yw–

(a) unrhyw drefniadau ar gyfer trin ac ystyried cwynion sydd neu y bu'n ofynnol eu sefydlu a'u gweithredu gan, yn ôl eu trefn, unrhyw rai o'r cyfarwyddiadau canlynol–

(i) Cyfarwyddiadau i Ymddiriedolaethau GIG a Byrddau Iechyd Lleol ar Weithdrefnau Cwynion Ysbytai a lofnodwyd ar 27 Mawrth 2003;

(ii) Cyfarwyddiadau i Fyrddau Iechyd Lleol ar Ymdrin â Chwynion ynghylch Ymarferwyr Gwasanaethau Iechyd Teuluol, Darparwyr Gwasanaethau Meddygol Personol a Darparwyr Gwasanaethau Deintyddol Personol ac eithrio'r Gwasanaethau Deintyddol Personol a Ddarperir gan Ymddiriedolaethau GIG a lofnodwyd ar 27 Mawrth 2003;

(iii) Cyfarwyddiadau Amrywiol i Fyrddau

(**1**) 2006 p.42.

(**2**) 1971 p.80.

(a) is a general medical services contractor;

(b) provides primary medical services in accordance with arrangements made under sections 41(2)(b) and 50 of the 2006 Act;

(c) is a general dental services contractor;

(d) provides primary dental services in accordance with arrangements under section 64 of the 2006 Act;

(e) provides general ophthalmic services in accordance with arrangements under section 71 of the 2006 Act;

(f) provides pharmaceutical services in accordance with arrangements under section 80 of the 2006 Act;

(g) provides local pharmaceutical services under pilot schemes pursuant to section 92 of the 2006 Act; or

(h) provides local pharmaceutical services pursuant to paragraph 1 of Schedule 7 to the 2006 Act;

"qualifying liability" ("*atebolrwydd cymwys*") means a liability in tort owed in respect of, or consequent upon, personal injury or loss arising out of or in connection with breach of a duty of care owed to any person in connection with the diagnosis of illness, or in the care or treatment of any patient–

(a) in consequence of any act or omission by a health care professional; and

(b) which arises in connection with the provision of qualifying services;

"relevant complaints procedure" ("*gweithdrefn gwynion berthnasol*") means–

(a) any arrangements for the handling and consideration of complaints that are required or have been required to be established and operated respectively by any of the following directions–

(i) Directions to NHS Trusts and Local Health Boards on Hospital Complaints Procedures signed on 27 March 2003;

(ii) Directions to Local Health Boards on Dealing with Complaints about Family Health Services Practitioners, Providers of Personal Medical Services and Providers of Personal Dental Services other than Personal Dental Services Provided by NHS Trusts signed on 27 March 2003;

(iii) Miscellaneous Directions to Local Health Boards for Dealing with Complaints signed on 27 March 2003(**1**);

(b) any arrangements for the handling and consideration of complaints that may at any time be or have been required by paragraph 28

(**1**) Copies of the Directions referred to in the definition of "relevant complaints procedure" may be obtained from the library at the Welsh Assembly Government, Cathays Park, Cardiff, CF10 3NQ.

Iechyd Lleol ar Ymdrin â Chwynion a lofnodwyd ar 27 Mawrth 2003(**1**);

(b) unrhyw drefniadau ar gyfer trin ac ystyried cwynion y gellid, ar unrhyw adeg, eu gwneud yn ofynnol, neu a wnaed yn ofynnol, gan baragraff 28 o Atodlen 2 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(**2**);

(c) unrhyw drefniadau ar gyfer trin ac ystyried cwynion y gellid, ar unrhyw adeg, gwneud yn ofynnol, neu a wnaed yn ofynnol, eu sefydlu a'u gweithredu gan, yn ôl eu trefn, unrhyw rai o'r darpariaethau canlynol–

(i) paragraff 39 o Atodlen 2 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992;

(ii) paragraff 22 o Atodlen 2A i Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992;

(iii) paragraff 90 o Atodlen 6 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004(**3**);

(iv) paragraff 8A o Atodlen 1 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Offthalmig Cyffredinol) 1986(**4**);

(v) paragraff 47 o Atodlen 3 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Deintyddol Cyffredinol) (Cymru) 2006(**5**);

(vi) paragraff 47 o Atodlen 3 i Reoliadau'r Gwasanaeth Iechyd Gwladol (Cytundebau Gwasanaethau Deintyddol Personol) (Cymru) 2006(**6**);

ystyr "niwed cymedrol neu ddifrifol" ("*moderate or severe harm*") yw niwed cymedrol neu ddifrifol a benderfynir yn unol â chanllawiau a ddyroddir at ddibenion y Rheoliadau hyn gan Weinidogion Cymru;

ystyr "plentyn" ("*child*") yw person nad yw wedi cyrraedd deunaw mlwydd oed;

ystyr "proffesiynolyn gofal iechyd" ("*health care professional*") yw aelod o broffesiwn (p'un a yw'n cael ei reoleiddio gan unrhyw ddeddfiad neu yn rhinwedd unrhyw ddeddfiad) sy'n ymwneud (yn llwyr neu yn rhannol) ag iechyd corfforol neu

(**1**) Gellir cael copïau o'r Cyfarwyddiadau y cyfeirir atynt yn y diffiniad o "gweithdrefn gwynion berthnasol" o'r llyfrgell yn Llywodraeth Cynulliad Cymru, Parc Cathays, Caerdydd CF10 3NQ.

(**2**) O.S. 1992/662.

(**3**) O.S. 2004/478 (Cy.48).

(**4**) O.S. 1986/975.

(**5**) O.S. 2006/490 (Cy.59).

(**6**) O.S. 2006/489 (Cy.58).

of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992(**1**);

(c) any arrangements for the handling and consideration of complaints that may at any time be or have been required to be established and operated respectively by any of the following provisions–

(i) paragraph 39 of Schedule 2 to the National Health Service (Pharmaceutical Services) Regulations 1992;

(ii) paragraph 22 of Schedule 2A to the National Health Service (Pharmaceutical Services) Regulations 1992;

(iii) paragraph 90 of Schedule 6 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**2**);

(iv) paragraph 8A of Schedule 1 to the National Health Service (General Ophthalmic Services) Regulations 1986(**3**);

(v) paragraph 47 of Schedule 3 to the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(**4**);

(vi) paragraph 47 of Schedule 3 to the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(**5**);

"responsible body" ("*corff cyfrifol*") means–

(a) a Welsh NHS body;

(b) a primary care provider; or

(c) an independent provider;

"staff" ("*staff*") means any person who is employed by or engaged to provide health care services for a responsible body;

"Welsh NHS body" ("*corff GIG Cymru*") means–

(a) a Local Health Board; or

(b) a National Health Service Trust managing a hospital or other establishment or facility wholly or mainly in Wales;

"working day" ("*diwrnod gwaith*") means a day except Saturday or Sunday, Christmas Day, Boxing Day, Good Friday, or a day which is a bank holiday in Wales under the Banking and Financial Dealings Act 1971(**6**).

(**1**) S.I. 1992/662.

(**2**) S.I. 2004/478 (W.48).

(**3**) S.I. 1986/975.

(**4**) S.I. 2006/490 (W.59).

(**5**) S.I. 2006/489 (W.58).

(**6**) 1971 c.80.

iechyd meddyliol unigolion;

ystyr "pryder" ("*concern*") yw unrhyw gŵyn; hysbysiad o ddigwyddiad sy'n ymwneud â diogelwch claf neu, ac eithrio mewn perthynas â phryderon a hysbysir ynghylch darparwyr gofal sylfaenol neu ddarparwyr annibynnol, hawliad am ddigollediad;

ystyr "staff" ("*staff*") yw unrhyw berson a gyflogir neu a gymerir ymlaen i ddarparu gwasanaethau gofal iechyd ar gyfer corff cyfrifol.

(2) At ddibenion Rhan 7, ystyr "gwasanaethau cymwys" ("*qualifying services*") yw gwasanaethau a ddarperir yn y Deyrnas Unedig fel rhan o'r gwasanaeth iechyd yng Nghymru (nid yw hyn yn cynnwys gwasanaethau a ddarperir yng Nghymru ac a gomisiynwyd fel rhan o'r gwasanaeth iechyd yn Lloegr, yr Alban neu Ogledd Iwerddon).

(3) At ddibenion rheoliad 3 a Rhannau 5 a 6, ystyr "gwasanaethau cymwys" ("*qualifying services*") yw gwasanaethau a ddarperir yng Nghymru fel rhan o'r gwasanaeth iechyd yng Nghymru (nid yw hyn yn cynnwys gwasanaethau a ddarperir yng Nghymru ac a gomisiynwyd fel rhan o'r gwasanaeth iechyd yn Lloegr, yr Alban neu Ogledd Iwerddon).

Egwyddorion cyffredinol ar gyfer trin ac ymchwilio i bryderon

3. Rhaid i unrhyw drefniadau a sefydlir o dan y Rheoliadau hyn ar gyfer trin ac ymchwilio i bryderon fod yn rhai a fydd yn sicrhau–

(a) mai un pwynt cyswllt yn unig a fydd ar gyfer cyflwyno pryderon;

(b) yr ymdrinnir â phryderon yn effeithlon ac agored;

(c) yr ymchwilir i'r pryderon yn gywir;

(ch) y gwneir darpariaeth i ganfod disgwyliadau'r person sy'n hysbysu'r pryder, ac i geisio cynnwys y person hwnnw yn y broses;

(d) bod personau sy'n hysbysu pryderon yn cael eu trin â pharch a chwrteisi;

(dd) bod personau sy'n hysbysu pryderon yn cael–

(i) gwybod bod cymorth ar gael i'w galluogi i fynd â'u pryder ymhellach;

(ii) cyngor, os oes ei angen, ynghylch lle y gallant gael cymorth o'r fath; a

(iii) enw'r person yn y corff cyfrifol perthnasol a fydd yn gweithredu fel eu cyswllt drwy gydol y cyfnod yr ymdrinnir â'u pryder;

(e) rhaid i gorff GIG Cymru ystyried gwneud cynnig o iawn yn unol â Rhan 6 os yw ei ymchwiliad i'r materion a godir gan bryder yn datgelu bod atebolrwydd cymwys;

(2) For the purposes of Part 7, "qualifying services" ("*gwasanaethau cymwys*") means services provided in the United Kingdom as part of the health service in Wales (this does not include services provided in Wales commissioned as part of the health service in England, Scotland or Northern Ireland).

(3) For the purposes of regulation 3 and Parts 5 and 6, "qualifying services" ("*gwasanaethau cymwys*") means services provided in Wales as part of the health service in Wales (this does not include services provided in Wales commissioned as part of the health service in England, Scotland or Northern Ireland).

General principles for the handling and investigation of concerns

3. Any arrangements set up under these Regulations for the handling and investigation of concerns must be such as to ensure that–

(a) there is a single point of entry for the submission of concerns;

(b) concerns are dealt with efficiently and openly;

(c) concerns are properly investigated;

(d) provision should be made to establish the expectations of the person notifying the concern and to seek to secure their involvement in the process;

(e) persons who notify concerns are treated with respect and courtesy;

(f) persons who notify concerns are advised of–

(i) the availability of assistance to enable them to pursue their concern;

(ii) advice as to where they may obtain such assistance, if it is required; and

(iii) the name of the person in the relevant responsible body who will act as their contact throughout the handling of their concern;

(g) a Welsh NHS body must give consideration to the making of an offer of redress in accordance with Part 6 where its investigation into the matters raised in a concern reveal that there is a qualifying liability;

(f) bod personau sy'n hysbysu pryderon yn cael ymateb prydlon a phriodol;

(ff) bod personau sy'n hysbysu pryderon yn cael gwybod canlyniad yr ymchwiliad;

(g) y gweithredir yn briodol yng ngoleuni canlyniad yr ymchwiliad; ac

(ng) y cymerir i ystyriaeth unrhyw ganllawiau a ddyroddir o bryd i'w gilydd gan Weinidogion Cymru.

(h) persons who notify concerns receive a timely and appropriate response;

(i) persons who notify concerns are advised of the outcome of the investigation;

(j) appropriate action is taken in the light of the outcome of the investigation; and

(k) account is taken of any guidance that may be issued from time to time by the Welsh Ministers.

RHAN 2

DYLETSWYDD I WNEUD TREFNIADAU AR GYFER TRIN AC YMCHWILIO I BRYDERON

Dyletswydd i wneud trefniadau

4. Rhaid i gorff cyfrifol wneud trefniadau yn unol â'r Rheoliadau hyn ar gyfer trin ac ymchwilio i bryderon ("trefniadau i ymdrin â phryderon").

Y trefniadau i'w cyhoeddi

5. Rhaid cyhoeddi'r trefniadau i ymdrin â phryderon mewn amrywiaeth o gyfryngau, fformatau ac ieithoedd, a rhaid rhoi copi yn ddi-dâl i unrhyw berson sy'n gofyn am gopi, yn y fformat y gofynnir amdano.

Goruchwyliaeth strategol o'r trefniadau

6.–(1) Rhaid i bob corff cyfrifol ddynodi person i fod yn gyfrifol am gynnal goruchwyliaeth strategol o weithrediad trefniadau'r corff o dan y Rheoliadau hyn, yn benodol er mwyn–

(a) sicrhau bod y corff cyfrifol yn cydymffurfio â'i drefniadau ar gyfer ymdrin â phryderon; a

(b) ymgymryd â'r swyddogaethau a bennir yn Rhan 8.

(2) Pan fo'r corff cyfrifol yn gorff GIG Cymru, rhaid i'r person hwn fod yn aelod nad yw'n swyddog neu'n gyfarwyddwr anweithredol y corff dan sylw, fel y bo'n briodol.

Y swyddog cyfrifol

7.–(1) Rhaid i bob corff cyfrifol ddynodi person, y cyfeirir ato yn y Rheoliadau hyn fel y swyddog cyfrifol, i ymgymryd â'r cyfrifoldeb cyffredinol am weithredu'r trefniadau o ddydd i ddydd i ymdrin â phryderon yn effeithiol ac mewn modd integredig.

(2) At ddibenion y rheoliad hwn, ystyr "modd integredig" yw yr ymgymerir â'r broses o drin

PART 2

DUTY TO MAKE ARRANGEMENTS FOR THE HANDLING AND INVESTIGATION OF CONCERNS

Duty to make arrangements

4. A responsible body must make arrangements in accordance with these Regulations for the handling and investigation of concerns ("arrangements for dealing with concerns").

Arrangements to be published

5. The arrangements for dealing with concerns must be published in a variety of media, formats and languages and a copy of the arrangements must be given free of charge to any person who requests it, in the format that has been requested.

Strategic oversight of the arrangements

6.–(1) Each responsible body must designate a person to be responsible for maintaining a strategic overview of its operation of the arrangements under these Regulations, in particular to–

(a) ensure that the responsible body complies with its arrangements for dealing with concerns; and

(b) undertake the functions set out in Part 8.

(2) Where the responsible body is a Welsh NHS body, this person must be one of its non-officer members or non-executive directors, as appropriate.

Responsible officer

7.–(1) Each responsible body must designate a person in these Regulations referred to as the responsible officer, to take overall responsibility for the effective day to day operation of the arrangements for dealing with concerns in an integrated manner.

(2) For the purposes of this regulation "integrated manner" means that the process for dealing with

pryderon, ac, os oes dyletswydd o dan y Rheoliadau i ystyried achosion o atebolrwydd cymwys, adrodd am reoli hawliadau, o dan yr un trefniant llywodraethu.

(3) Rhaid i'r swyddog cyfrifol fod–

(a) yn achos corff GIG Cymru, yn aelod sy'n swyddog neu'n gyfarwyddwr gweithredol o'r corff hwnnw, fel y bo'n briodol;

(b) yn achos unrhyw gorff cyfrifol arall, y person sy'n gweithredu fel prif swyddog gweithredol y corff hwnnw neu, os nad oes un–

(i) y person sy'n unig berchennog y corff cyfrifol;

(ii) os yw'r corff cyfrifol yn bartneriaeth, partner; neu

(iii) mewn unrhyw achos arall, cyfarwyddwr y corff cyfrifol, neu berson sy'n gyfrifol am reoli'r corff cyfrifol.

(4) Caniateir i swyddogaethau'r swyddog cyfrifol gael eu cyflawni gan y person hwnnw neu gan unrhyw berson a awdurdodir gan y corff cyfrifol i weithredu ar ran y swyddog cyfrifol, ar yr amod bod y person a awdurdodir felly o dan reolaeth a goruchwyliaeth uniongyrchol y swyddog cyfrifol.

Yr uwch-reolwr ymchwiliadau

8.–(1) Rhaid i bob corff cyfrifol ddynodi o leiaf un person, y cyfeirir ato yn y Rheoliadau hyn fel uwch-reolwr ymchwiliadau, i ymgymryd â'r cyfrifoldeb am drin ac ystyried pryderon a hysbysir yn unol â'r trefniadau ar gyfer trin pryderon, ac yn benodol–

(a) cyflawni swyddogaethau uwch-reolwr ymchwiliadau o dan y trefniadau i ymdrin â phryderon;

(b) cyflawni pa bynnag swyddogaethau eraill ynglŷn â thrin ac ystyried pryderon ag y bo'n ofynnol gan y corff cyfrifol; ac

(c) cydweithredu â pha bynnag bersonau neu gyrff eraill ag y bo'n angenrheidiol, i hwyluso trin ac ystyried pryderon.

(2) Rhaid i'r corff cyfrifol sicrhau bod gan yr uwch-reolwr ymchwiliadau a benodir ganddo staff sy'n ddigonol o ran nifer a lefel ofynnol o gyfrifoldeb i'w gynorthwyo i gyflawni ei swyddogaethau, a bod y cyfryw aelodau o'r staff yn cael hyfforddiant digonol i'w galluogi i gyflawni eu cyfrifoldebau o dan y trefniadau ar gyfer ymdrin â phryderon.

(3) Caniateir i swyddogaethau uwch-reolwr ymchwiliadau o dan baragraff (1) gael eu cyflawni ganddo yn bersonol neu gan berson neu bersonau a awdurdodir gan y corff cyfrifol i weithredu ar ran yr uwch-reolwr ymchwiliadau.

concerns, and, if there is a duty under the Regulations to consider qualifying liabilities, claims management reporting are dealt with under a single governance arrangement.

(3) The responsible officer is to be–

(a) in the case of a Welsh NHS body, a person who is an officer member or executive director of that body, as appropriate;

(b) in the case of any other responsible body, the person who acts as the chief executive officer of that body or, if there is none–

(i) the person who is the sole proprietor of the responsible body;

(ii) where the responsible body is a partnership, a partner; or

(iii) in any other case, a director of the responsible body, or a person who is responsible for managing the responsible body.

(4) The functions of the responsible officer may be performed by that person or by any person authorised by the responsible body to act on his or her behalf provided that the person so authorised is under the direct control and supervision of the responsible officer.

Senior investigations manager

8.–(1) Each responsible body must designate at least one person, in these Regulations referred to as a senior investigations manager, to undertake responsibility for the handling and consideration of concerns notified in accordance with the arrangements for handling concerns and in particular to–

(a) perform the functions of a senior investigations manager under the arrangements for dealing with concerns;

(b) perform such other functions relating to the handling and consideration of concerns as the responsible body may require; and

(c) co-operate with such other persons or bodies as may be necessary to facilitate the handling and consideration of concerns.

(2) The responsible body must ensure that the senior investigations manager appointed by that body has a sufficient number of staff of the required level of seniority to assist in the carrying out of his or her functions and that such members of staff receive adequate training to enable them to fulfil their responsibilities under the arrangements for dealing with concerns.

(3) The functions of a senior investigations manager under paragraph (1) may be performed personally or by a person or persons authorised by the responsible body to act on behalf of the senior investigations manager.

(4) Caniateir i swyddogaethau uwch-reolwr ymchwiliadau gael eu cyflawni gan yr uwch-reolwr ymchwiliadau a ddynodwyd gan gorff cyfrifol arall o dan baragraff (1).

(4) The functions of a senior investigations manager may be carried out by the senior investigations manager designated by another responsible body under paragraph (1).

Gwybodaeth a hyfforddiant i'r staff

9. Rhaid i bob corff cyfrifol sicrhau bod ei staff yn cael gwybodaeth a hyfforddiant priodol ynglŷn â gweithredu'r trefniadau ar gyfer adrodd, trin ac ymchwilio i bryderon.

Information and training for staff

9. Each responsible body must ensure that its staff are informed about and receive appropriate training in respect of the operation of the arrangements for the reporting, handling and investigation of concerns.

RHAN 3

NATUR A CHWMPAS Y TREFNIADAU AR GYFER TRIN PRYDERON

Gofyniad i ystyried pryderon

10. Yn ddarostyngedig i reoliad 14, rhaid i gorff cyfrifol drin pryder yn unol â'r trefniadau ar gyfer ymdrin â phryderon a bennir yn y Rheoliadau hyn os hysbysir y pryder ar neu ar ôl 1 Ebrill 2011–

(a) yn unol â rheoliad 11;

(b) gan berson fel a bennir yn unol â rheoliad 12;

(c) ynghylch mater a bennir yn rheoliad 13; ac

(ch) o fewn y cyfnod a bennir yn rheoliad 15.

Hysbysu pryderon

11.–(1) Caniateir hysbysu pryder–

(a) mewn ysgrifen;

(b) yn electronig; neu

(c) ar lafar, naill ai dros y teleffon neu'n bersonol, i unrhyw aelod o staff y corff cyfrifol y mae arfer ei swyddogaethau yn destun y pryder.

(2) Yn ddarostyngedig i reoliad 14(1)(dd) pan hysbysir pryder ar lafar, rhaid i'r aelod o staff y corff cyfrifol yr hysbysir y pryder iddo–

(a) wneud cofnod ysgrifenedig o'r pryder; a

(b) darparu copi o'r cofnod ysgrifenedig i'r person a hysbysodd y pryder.

Personau y caniateir iddynt hysbysu pryderon

12.–(1) Caiff y canlynol hysbysu pryder–

(a) person sy'n cael, neu sydd wedi cael, gwasanaethau gan gorff cyfrifol, ynglŷn â'r gwasanaethau a gaiff neu y bu'n eu cael;

(b) unrhyw berson yr effeithir arno, neu y bo'n

PART 3

NATURE AND SCOPE OF THE ARRANGEMENTS FOR HANDLING CONCERNS

Requirement to consider concerns

10. Subject to regulation 14, a responsible body must handle a concern in accordance with the arrangements for handling concerns set out in these Regulations if it is notified on or after the 1 April 2011–

(a) in accordance with regulation 11;

(b) by a person specified in accordance with regulation 12;

(c) about a matter specified in regulation 13; and

(d) within the period specified in regulation 15.

Notification of concerns

11.–(1) A concern may be notified–

(a) in writing;

(b) electronically; or

(c) verbally, either by telephone or in person, to any member of the staff of the responsible body, the exercise of whose functions is the subject of the concern.

(2) Subject to regulation 14(1)(f), where a concern is notified verbally, the member of staff of the responsible body to whom the concern has been notified must–

(a) make a written record of the concern; and

(b) provide a copy of the written record to the person who notified the concern.

Persons who may notify concerns

12.–(1) A concern may be notified by–

(a) a person who is receiving or has received services from a responsible body in relation to the services being received or having been received;

(b) any person who is affected, or likely to be

debygol yr effeithir arno, gan weithred, anwaith neu benderfyniad corff cyfrifol y mae arfer ei swyddogaethau'n destun y pryder;

(c) aelod nad yw'n swyddog neu gyfarwyddwr anweithredol corff cyfrifol;

(ch) aelod o staff corff cyfrifol; neu

(d) partner mewn corff cyfrifol.

(2) Caiff person (y cyfeirir ato yn y rheoliad hwn fel cynrychiolydd) hysbysu pryder os yw'n gweithredu ar ran person a grybwyllir ym mharagraff (1)–

(a) a fu farw;

(b) sy'n blentyn;

(c) sy'n analluog i hysbysu'r pryder ei hunan oherwydd diffyg galluedd, yn yr ystyr a roddir i "capacity" yn Neddf Galluedd Meddyliol 2005(**1**); neu

(ch) sydd wedi gofyn i'r cynrychiolydd weithredu ar ei ran.

(3) Pan fo cynrychiolydd yn hysbysu pryder ar ran plentyn, rhaid i'r corff cyfrifol yr hysbyswyd y pryder iddo–

(a) peidio ag ystyried y pryder oni fodlonir y corff cyfrifol bod sail ddigonol dros hysbysu'r pryder gan gynrychiolydd yn hytrach na chan y plentyn; a

(b) os na fodlonir ef felly, rhaid iddo hysbysu'r cynrychiolydd mewn ysgrifen, gan nodi'r rheswm dros ei benderfyniad.

(4) Pan hysbysir pryder gan blentyn, rhaid i'r corff cyfrifol ddarparu pa bynnag gymorth i'r plentyn ag y bydd ei angen ar y plentyn yn rhesymol, er mwyn mynd ymlaen â'r pryder.

(5) Mae'r paragraff hwn yn gymwys–

(a) pan fo cynrychiolydd yn hysbysu pryder ar ran–

(i) plentyn; neu

(ii) person sydd â diffyg galluedd, yn yr ystyr a roddir i "capacity" yn Neddf Galluedd Meddyliol 2005; a

(b) pan fo'r corff cyfrifol, yr hysbyswyd y pryder iddo, wedi ei fodloni bod sail resymol dros ddod i'r casgliad nad yw'r cynrychiolydd yn berson addas i weithredu fel cynrychiolydd, neu nad yw'n bwrw ymlaen â'r pryder er budd gorau'r person yr hysbyswyd y pryder ar ei ran.

(6) Pan fo paragraff (5) yn gymwys–

(a) ac eithrio pan fo is-baragraff (6)(b) hefyd yn gymwys, caniateir peidio ag ystyried y pryder, neu beidio â'i ystyried ymhellach, yn unol â threfniadau a wnaed o dan y Rheoliadau hyn, a rhaid i'r corff cyfrifol hysbysu'r cynrychiolydd mewn ysgrifen, gan nodi'r rheswm am y

(**1**) 2005 p.9.

affected by the action, omission or decision of a responsible body the exercise of whose functions is the subject of the concern;

(c) a non-officer member or a non-executive director of a responsible body;

(d) a member of the staff of a responsible body; or

(e) a partner in a responsible body.

(2) A concern may be notified by a person (in this regulation referred to as a representative) acting on behalf of a person mentioned in paragraph (1) who–

(a) has died;

(b) is a child;

(c) is unable to notify the concern themselves because they lack capacity within the meaning of the Mental Capacity Act 2005(**1**); or

(d) has requested the representative to act on their behalf.

(3) Where a representative notifies a concern on behalf of a child, the responsible body to which the concern has been notified–

(a) must not consider the concern unless it is satisfied that there are reasonable grounds for the concern being notified by a representative instead of the child; and

(b) if it is not so satisfied, must notify the representative in writing and state the reason for its decision.

(4) Where a concern is notified by a child, the responsible body must provide the child with such assistance as the child may reasonably require in order to pursue the concern.

(5) This paragraph applies where–

(a) a representative notifies a concern on behalf of–

(i) a child; or

(ii) a person who lacks capacity within the meaning of the Mental Capacity Act 2005; and

(b) the responsible body to which the concern has been notified is satisfied that there are reasonable grounds to conclude that the representative is not a suitable person to act as representative or is not pursuing the concern in the best interests of the person on whose behalf the concern has been notified.

(6) Where paragraph (5) applies–

(a) save where sub-paragraph (6)(b) also applies, the concern may not be considered or further considered in accordance with arrangements made under these Regulations and the responsible body must notify the representative in writing and state the reason

(**1**) 2005 c.9.

penderfyniad;

(b) os yw'r corff cyfrifol wedi ei fodloni bod gwneud hynny'n angenrheidiol, caiff barhau i ymchwilio i unrhyw fater a godir gan y pryder a hysbyswyd yn unol â pharagraff (5), ond o dan yr amgylchiadau hynny, nid oes unrhyw rwymedigaeth arno i ddarparu ymateb yn unol â rheoliad 24 onid yw o'r farn y byddai'n rhesymol gwneud hynny.

(7) Ac eithrio pan fo paragraff (8) yn gymwys, os hysbysir pryder gan aelod o staff y corff cyfrifol ac os yw ymchwiliad dechreuol y corff cyfrifol yn canfod bod niwed cymedrol neu ddifrifol neu farwolaeth wedi digwydd, rhaid i'r corff cyfrifol hysbysu'r claf y mae'r pryder yn gysylltiedig ag ef, neu ei gynrychiolydd, o'r hysbysiad o bryder, a chynnwys y claf, neu ei gynrychiolydd, yn yr ymchwiliad i'r pryder yn unol â Rhan 5.

(8) Os, ym marn y corff cyfrifol, na fyddai er budd y claf pe rhoddid gwybod i'r claf am y pryder, neu pe cynhwysid y claf yn yr ymchwiliad i'r pryder, rhaid i'r corff cyfrifol–

(a) gwneud cofnod ysgrifenedig o'r penderfyniad hwnnw a'r rhesymau drosto; a

(b) cadw'r penderfyniad hwnnw dan arolwg yn ystod yr ymchwiliad i'r pryder.

(9) Yn y Rheoliadau hyn, mae unrhyw gyfeiriad at berson sy'n hysbysu pryder neu'n ceisio iawn yn cynnwys cyfeiriad at gynrychiolydd y person hwnnw.

Materion y caniateir hysbysu pryderon yn eu cylch

13. Caniateir hysbysu pryder yn unol â'r Rheoliadau hyn–

(a) wrth gorff GIG Cymru ynglŷn ag unrhyw fater sy'n gysylltiedig ag arfer ei swyddogaethau;

(b) wrth ddarparwr gofal sylfaenol ynghylch y ddarpariaeth o wasanaethau ganddo o dan gontract neu drefniadau gyda chorff GIG Cymru;

(c) wrth ddarparwr annibynnol ynglŷn â'r ddarpariaeth o wasanaethau ganddo o dan drefniadau gyda chorff GIG Cymru; neu

(ch) ar yr amod y bodlonir y gofynion a bennir yn rheoliad 18, i Fwrdd Iechyd Lleol ynghylch unrhyw fater sy'n gysylltiedig â'r ddarpariaeth o wasanaethau gan ddarparwr gofal sylfaenol o dan gontract neu drefniadau gyda'r Bwrdd Iechyd Lleol.

Materion a phryderon a eithrir rhag eu hystyried o dan y trefniadau

14.–(1) Mae'r canlynol yn faterion a phryderon sydd wedi eu heithrio o briod faes y trefniadau sy'n ofynnol o dan y Rheoliadau hyn–

(a) pryder a hysbysir gan ddarparwr gofal

for the decision;

(b) if the responsible body is satisfied that it is necessary to do so, it may continue to investigate any issue raised by the concern notified in accordance with paragraph (5), but in these circumstances it is under no obligation to provide a response in accordance with regulation 24, unless it considers that it is reasonable to do so.

(7) Unless paragraph (8) applies, where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern and involve the patient, or his or her representative, in the investigation of the concern in accordance with Part 5.

(8) Where, in the opinion of the responsible body, it would not be in the interests of the patient to be informed of or involved in the investigation of the concern it must–

(a) make a written record of this decision and the reasons for it; and

(b) keep the decision under review during the investigation of concern.

(9) In these Regulations any reference to a person who notifies a concern or is seeking redress includes a reference to a representative of that person.

Matters about which concerns may be notified

13. A concern may be notified in accordance with these Regulations to–

(a) a Welsh NHS body about any matter connected with the exercise of its functions;

(b) a primary care provider about the provision of services by it under a contract or arrangements with a Welsh NHS body;

(c) an independent provider about the provision of services by it under arrangements with a Welsh NHS body; or

(d) provided that the requirements set out in regulation 18 are met, a Local Health Board about any matter connected with the provision of services by a primary care provider under a contract or arrangements with the Local Health Board.

Matters and concerns excluded from consideration under the arrangements

14.–(1) The following are matters and concerns which are excluded from the scope of the arrangements required under these Regulations–

(a) a concern notified by a primary care provider

sylfaenol, sy'n ymwneud â'r contract neu'r trefniadau y mae'n darparu gwasanaethau gofal sylfaenol odano neu odanynt;

(b) pryder a hysbysir gan aelod o staff corff cyfrifol ynghylch unrhyw fater sy'n ymwneud â chontract cyflogaeth y person hwnnw;

(c) pryder sydd neu a fu'n destun ymchwiliad gan Ombwdsmon Gwasanaethau Cyhoeddus Cymru(**1**);

(ch) pryder sy'n codi o fethiant honedig gan gorff cyfrifol i gydymffurfio â chais am wybodaeth o dan Ddeddf Rhyddid Gwybodaeth 2000(**2**);

(d) achos disgyblu y mae corff cyfrifol yn ei ddwyn, neu'n bwriadu ei ddwyn, sy'n ganlyniad, neu sy'n tarddu o, ymchwiliad i bryder a hysbyswyd yn unol â threfniadau i ymdrin â phryderon a wnaed o dan y Rheoliadau hyn;

(dd) pryder a hysbysir ar lafar, naill ai'n bersonol neu dros y teleffon, ac a ddatrysir er boddhad i'r person a hysbysodd y pryder, ddim hwyrach na'r diwrnod gwaith nesaf ar ôl y diwrnod y hysbyswyd y pryder;

(e) pryder sydd â'r un testun â phryder a hysbyswyd yn flaenorol, ac a ddatryswyd yn unol ag is-baragraff (dd), oni fydd y corff cyfrifol o'r farn y byddai'n rhesymol ailagor ystyriaeth o'r pryder hwnnw a chynnal ymchwiliad yn unol â Rhan 5;

(f) pryder yr ystyriwyd ei destun eisoes yn unol â threfniadau a wnaed o dan–

(i) y Rheoliadau hyn; neu

(ii) unrhyw weithdrefn gwynion berthnasol mewn cysylltiad â chwyn a wnaed cyn 1 Ebrill 2011;

(ff) pryder y mae ei destun, neu y daw ei destun, yn destun achos sifil; neu

(g) pryder y mae ei destun, neu y daw ei destun, yn bryder mewn perthynas â chais am driniaeth i glaf unigol.

(2) Yn ddarostyngedig i baragraff (3), pan fo pryder neu fater yn bryder neu fater a bennir ym mharagraff (1), a chorff cyfrifol yn gwneud penderfyniad i'r perwyl hwnnw, rhaid i'r corff cyfrifol, cyn gynted ag y bo'n rhesymol ymarferol, hysbysu'r person a hysbysodd y pryder neu fater o'i benderfyniad, mewn ysgrifen, gan roi'r rheswm dros y penderfyniad.

(**1**) Pryder yr ymchwilir iddo neu'r ymchwiliwyd yn ei gylch yn unol â'r darpariaethau perthnasol yn Neddf Ombwdsmon Gwasanaethau Cyhoeddus (Cymru) 2005. 2005 p.10.

(**2**) 2000 p.36.

which relates to the contract or arrangements under which it provides primary care services;

(b) a concern notified by a member of staff of a responsible body about any matter relating to that person's contract of employment;

(c) a concern which is being or has been investigated by the Public Services Ombudsman for Wales(**1**);

(d) a concern arising out of an alleged failure by a responsible body to comply with a request for information under the Freedom of Information Act 2000(**2**);

(e) disciplinary proceedings which a responsible body is taking, or is proposing to take, as a result of, or arising from the investigation of, a concern notified in accordance with arrangements for dealing with concerns made under these Regulations;

(f) a concern which is notified verbally, either in person, or on the telephone and is resolved to the satisfaction of the person who notified the concern not later than the next working day after the day on which the concern was notified;

(g) a concern, the subject matter of which is the same as that of a concern that has previously been notified and resolved in accordance with sub-paragraph (f) unless the responsible body considers that it is reasonable to re-open the consideration of the concern and to undertake an investigation in accordance with Part 5;

(h) a concern, the subject matter of which has previously been considered in accordance with arrangements made under–

(i) these Regulations; or

(ii) any relevant complaints procedure in relation to a complaint which was made before 1 April 2011;

(i) a concern, the subject matter of which is, or becomes, the subject of civil proceedings; or

(j) a concern the subject matter of which is, or becomes, a concern related to an individual patient treatment request.

(2) Subject to paragraph (3), where a concern or matter is a concern or matter specified in paragraph (1), and a responsible body makes a decision to that effect, the responsible body must as soon as reasonably practicable notify in writing the person who notified the concern or matter of its decision and the reason for its decision.

(**1**) A concern which is being or has been investigated in accordance with the relevant provisions of the Public Services Ombudsman (Wales) Act 2005. 2005 c.10.

(**2**) 2000 c.36.

(3) Nid yw paragraff (2) yn gymwys i fater a bennir yn is-baragraff (dd) o baragraff (1).

(4) Pan fo mater a bennir ym mharagraff (1) yn rhan o fater arall nas pennir felly, neu'n gysylltiedig â mater arall o'r fath, nid oes dim yn y rheoliad hwn sy'n rhwystro'r mater arall hwnnw rhag cael ei ystyried fel pryder a hysbyswyd yn unol â threfniadau a wnaed o dan y Rheoliadau hyn.

Terfyn amser ar gyfer hysbysu pryderon

15.–(1) Yn ddarostyngedig i baragraff (2), rhaid hysbysu pryder ddim hwyrach na deuddeng mis ar ôl–

(a) y dyddiad y digwyddodd y mater sy'n destun y pryder; neu

(b) os yw'n ddiweddarach, y dyddiad y daeth y mater sy'n destun y pryder i sylw'r person sy'n hysbysu'r pryder.

(2) Yn ddarostyngedig i baragraff (3), ni fydd y terfyn amser ym mharagraff (1) yn gymwys os bodlonir y corff cyfrifol–

(a) bod gan y person sy'n hysbysu'r pryder resymau da dros beidio â hysbysu'r pryder o fewn y terfyn amser hwnnw; a

(b) er gwaethaf yr oedi, bod modd o hyd ymchwilio i'r pryder yn effeithiol a theg.

(3) Ni chaniateir hysbysu pryder ar ôl cyfnod o dair blynedd neu ragor ar ôl dyddiad y digwyddiad sy'n destun y pryder, neu, os yw'n yn ddiweddarach, cyfnod o dair blynedd neu ragor ar ôl i'r mater sy'n destun y pryder ddod i sylw'r claf.

(4) Mewn perthynas â pharagraffau (1) a (2), mae cyfeiriad at y dyddiad y daeth y mater sy'n destun y pryder i sylw'r person sy'n hysbysu'r pryder, pan fo'r claf wedi dewis cael cynrychiolydd i weithredu ar ei ran yn unol â rheoliad 12(2)(ch), yn gyfeiriad at y dyddiad y daeth y mater i sylw'r claf, ac nid y dyddiad y daeth i sylw'r cynrychiolydd sy'n hysbysu'r pryder ar ran y claf.

Tynnu pryderon yn ôl

16.–(1) Caiff y person a hysbysodd bryder dynnu'r pryder yn ôl ar unrhyw adeg, a chaiff wneud hynny–

(a) mewn ysgrifen;

(b) yn electronig; neu

(c) ar lafar, naill ai dros y teleffon neu'n bersonol.

(2) Rhaid i'r corff cyfrifol, cyn gynted ag y bo'n ymarferol, ysgrifennu at y person a dynnodd y pryder yn ôl ar lafar i gadarnhau bod y pryder wedi ei dynnu yn ôl ar lafar.

(3) Pan fo pryder wedi ei dynnu yn ôl, caiff corff cyfrifol barhau, er gwaethaf hynny, i ymchwilio yn

(3) Paragraph (2) does not apply to a matter specified in sub-paragraph (f) of paragraph (1).

(4) Where a matter specified in paragraph (1) is part of, or is connected with, another matter which is not so specified, nothing in this regulation prevents that other matter being considered as a concern notified in accordance with arrangements made under these Regulations.

Time limit for notification of concerns

15.–(1) Subject to paragraph (2), a concern must be notified not later than twelve months after–

(a) the date on which the matter which is the subject of the concern occurred; or

(b) if later, the date on which the matter which is the subject of the concern came to the notice of the person notifying the concern.

(2) Subject to paragraph (3), the time limit in paragraph (1) will not apply if the responsible body is satisfied that–

(a) the person notifying the concern had good reasons for not notifying the concern within that time limit; and

(b) notwithstanding the delay, it is still possible to investigate the concern effectively and fairly.

(3) A concern may not be notified three or more years after the date on which the matter which is the subject of the concern occurred or, if later, three or more years from the date on which the matter which is the subject of the concern came to the notice of the patient.

(4) In respect of paragraphs (1) and (2), a reference to the date on which the matter which is the subject of the concern came to the notice of the person notifying the concern is, where a patient has opted to have a representative act on his or her behalf in accordance with regulation 12(2)(d), a reference to the patient's date of knowledge and not to that of the representative who is notifying the concern on the patient's behalf.

Withdrawal of concerns

16.–(1) A concern may be withdrawn at any time by the person who notified the concern and the withdrawal may be notified–

(a) in writing;

(b) electronically; or

(c) verbally, either by telephone or in person.

(2) The responsible body must as soon as practicable write to the person who has withdrawn a concern verbally to confirm the verbal withdrawal of a concern.

(3) Where a concern has been withdrawn, a responsible body may nevertheless continue to

unol â Rhan 5 i unrhyw faterion a godwyd gan bryder, os yw'r corff cyfrifol o'r farn bod angen gwneud hynny.

investigate any issues raised by a concern in accordance with Part 5, should the responsible body consider that it is necessary to do so.

RHAN 4

PRYDERON SY'N YMWNEUD Â CHYRFF CYFRIFOL ERAILL

Pryderon sy'n ymwneud â mwy nag un corff cyfrifol

17.–(1) Mae'r rheoliad hwn yn gymwys mewn unrhyw achos–

(a) pan fo'r person sy'n hysbysu pryder wedi codi materion sy'n ymwneud â'r modd yr arferir swyddogaethau mwy nag un corff cyfrifol; neu

(b) pan yw'n ymddangos i gorff cyfrifol ("y corff cyntaf") bod, neu y gall fod, pryder a hysbyswyd iddo yn bryder sy'n ymwneud ag arfer swyddogaethau corff cyfrifol arall ("yr ail gorff").

(2) Pan fo paragraff (1)(b) yn gymwys, os yw'r pryder wedi ei hysbysu gan glaf neu, yn unol â rheoliad 12, gan gynrychiolydd y claf, rhaid i'r corff cyntaf–

(a) o fewn dau ddiwrnod gwaith ar ôl cael y hysbysiad o bryder, gofyn am ganiatâd y person a hysbysodd y pryder i hysbysu'r ail gorff neu gyrff sy'n gysylltiedig; a

(b) hysbysu'r ail gorff neu gyrff sy'n gysylltiedig o fewn dau ddiwrnod gwaith ar ôl cael y caniatâd a grybwyllir yn is-baragraff (a).

(3) Rhaid i'r corff cyntaf a'r ail gorff neu gyrff gydweithredu at y diben o–

(a) cydgysylltu'r gwaith o drin ac ystyried y pryder; a

(b) sicrhau bod y person a hysbysodd y pryder yn cael ymateb cydgysylltiedig i'r pryder neu bryderon a hysbyswyd ganddo.

(4) Mae'r ddyletswydd i gydweithredu o dan baragraff (3) yn cynnwys, yn benodol, dyletswydd ar bob corff–

(a) i geisio cytuno ar ba un o'r cyrff cysylltiedig a ddylai arwain o ran–

(i) cydgysylltu'r gwaith o drin ac ystyried y pryder; a

(ii) cyfathrebu â'r person a hysbysodd y pryder;

(b) ar yr amod y caniateir y caniatadau priodol, i ddarparu gwybodaeth berthnasol i'r corff neu

PART 4

CONCERNS WHICH INVOLVE OTHER RESPONSIBLE BODIES

Concerns involving more than one responsible body

17.–(1) This regulation applies in any case where–

(a) the person who notifies a concern has raised issues which involve the exercise of functions by more than one responsible body; or

(b) it appears to a responsible body ("the first body") that a concern which has been notified to it is or may be a concern which relates to the exercise of functions of another responsible body ("the second body").

(2) Where paragraph (1)(b) applies the first body must, if the concern has been notified by a patient or, in accordance with regulation 12, his or her representative–

(a) within two working days of receipt of the notification of the concern, seek the consent of the person who notified the concern to the notification of the second body or bodies involved; and

(b) notify the second body or bodies involved within two working days of receipt of the consent mentioned in sub-paragraph (a).

(3) The first body and the second body or bodies must co-operate for the purposes of–

(a) co-ordinating the handling and consideration of the concern; and

(b) ensuring that the person who notified the concern receives a co-ordinated response to the concern or concerns that he or she has notified.

(4) The duty to co-operate under paragraph (3) includes, in particular, a duty for each body–

(a) to seek to agree which of the bodies involved should take the lead in–

(i) co-ordinating the handling and consideration of the concern; and

(ii) communicating with the person who notified the concern;

(b) subject to obtaining the appropriate consents, to provide to the other body or bodies

gyrff eraill ar gyfer trin ac ystyried y pryder, pan fo corff arall yn gofyn yn rhesymol am yr wybodaeth; ac

(c) i sicrhau y caiff ei gynrychioli mewn unrhyw gyfarfod y gofynnir amdano yn rhesymol mewn cysylltiad â thrin ac ystyried y pryder.

information relevant to the handling and consideration of the concern which is reasonably requested by another body; and

(c) to ensure that it is represented at any meeting reasonably required in connection with the handling and consideration of the concern.

Pryderon sy'n ymwneud â darparwyr gofal sylfaenol

18. Mae'r rheoliad hwn a rheoliadau 19, 20 a 21 yn gymwys i bryder–

(a) a hysbysir i Fwrdd Iechyd Lleol ar neu ar ôl 1 Ebrill 2011 yn unol â threfniadau i ymdrin â phryderon, a wnaed o dan y Rheoliadau hyn;

(b) ynghylch y gwasanaethau a ddarperir gan ddarparwr gofal sylfaenol o dan gontract neu drefniadau gyda Bwrdd Iechyd Lleol; ac

(c) nad yw wedi ei eithrio yn unol â rheoliad 14 rhag ei ystyried.

Concerns involving primary care providers

18. This regulation and regulations 19, 20 and 21 apply to a concern–

(a) notified to a Local Health Board on or after 1 April 2011 in accordance with arrangements for dealing with concerns made under these Regulations;

(b) about the services provided by a primary care provider under a contract or arrangements with a Local Health Board; and

(c) which is not excluded from consideration in accordance with regulation 14.

Camau sydd i'w cymryd pan hysbysir pryder i Fwrdd Iechyd Lleol ynghylch gwasanaethau a ddarperir gan ddarparwr gofal sylfaenol

19.–(1) Pan fo Bwrdd Iechyd Lleol yn cael hysbysiad o bryder gan neu ar ran person sy'n cael neu sydd wedi cael gwasanaethau gan ddarparwr gofal sylfaenol, rhaid iddo benderfynu a yw'r pryder, ym marn y Bwrdd Iechyd Lleol, yn un priodol i'r Bwrdd Iechyd Lleol ei ystyried, ynteu a fyddai'n fwy priodol iddo gael ei ystyried gan y darparwr gofal sylfaenol sy'n destun y pryder.

(2) Cyn gwneud penderfyniad rhaid i'r Bwrdd Iechyd Lleol ganfod gan y person a hysbysodd y pryder–

(a) pa un a ystyriwyd y pryder gan y darparwr gofal sylfaenol ai peidio, ac os do, pa un a ddyroddwyd ymateb gan y darparwr yn unol â rheoliad 24; a

(b) pa un a yw'r person a hysbysodd y pryder yn rhoi caniatâd ai peidio ag anfon manylion o'r pryder at y darparwr gofal sylfaenol sy'n destun y pryder.

(3) Os dyroddwyd ymateb gan y darparwr gofal sylfaenol yn unol â rheoliad 24, rhaid i'r Bwrdd Iechyd Lleol beidio ag ystyried y pryder.

(4) Os nad yw'r person sy'n hysbysu'r pryder yn rhoi caniatâd i'r Bwrdd Iechyd Lleol anfon manylion o'r pryder at y darparwr gofal sylfaenol, rhaid i'r Bwrdd Iechyd Lleol beidio ag ymchwilio i'r pryder, oni fyddai hysbysu'r darparwr gofal sylfaenol o'r pryder, ym marn resymol y Bwrdd Iechyd Lleol, yn rhagfarnu ei ystyriaeth o'r pryder.

Action to be taken where a Local Health Board receives notification of a concern about services provided by a primary care provider

19.–(1) When a Local Health Board receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider it must determine whether, in its opinion, the concern is appropriate for it to consider or whether it is more appropriate for the primary care provider that is the subject of the concern to consider.

(2) Before making a decision the Local Health Board must determine from the person who notified the concern, whether–

(a) the concern has been considered by the primary care provider, and if so, whether a response has been issued by the provider in accordance with regulation 24; and

(b) the person who notified the concern consents to details of the concern being sent to the primary care provider who is the subject of the concern.

(3) If a response has been issued by the primary care provider in accordance with regulation 24, the Local Health Board must not consider the concern.

(4) If the person notifying the concern does not consent to the Local Health Board sending details of the concern to the primary care provider, the Local Health Board must not investigate the concern unless notifying the primary care provider of the concern would, in the reasonable opinion of the Local Health Board, prejudice its consideration of the concern.

Camau sydd i'w cymryd pan hysbysir pryder i Fwrdd Iechyd Lleol gan ddarparwr gofal sylfaenol

20.–(1) Pan fo Bwrdd Iechyd Lleol yn cael hysbysiad o bryder gan ddarparwr gofal sylfaenol, rhaid i'r Bwrdd Iechyd Lleol benderfynu a yw'r pryder, ym marn y Bwrdd Iechyd Lleol, yn un priodol i'r Bwrdd Iechyd Lleol ei ystyried, ynteu a fyddai'n fwy priodol i'r pryder gael ei ystyried gan y darparwr gofal sylfaenol sy'n destun y pryder.

(2) Cyn gwneud penderfyniad rhaid i'r Bwrdd Iechyd Lleol–

(a) canfod a yw'r pryder wedi ei ystyried gan y darparwr gofal sylfaenol ai peidio, ac os ydyw, a ddyroddwyd ymateb gan y darparwr yn unol â rheoliad 24; a

(b) canfod a yw'r person a hysbysodd y pryder yn rhoi caniatâd i'r Bwrdd Iechyd Lleol ystyried y pryder ai peidio, os yw'r Bwrdd Iechyd Lleol yn penderfynu, yn unol â pharagraff (2), y byddai'n briodol i'r Bwrdd Iechyd Lleol wneud hynny.

(3) Os dyroddwyd ymateb gan y darparwr yn unol â rheoliad 24, rhaid i'r Bwrdd Iechyd Lleol beidio ag ystyried y pryder.

(4) Os nad yw'r person a hysbysodd y pryder yn rhoi caniatâd i'r Bwrdd Iechyd Lleol ymdrin â'r pryder, rhaid i'r Bwrdd Iechyd Lleol beidio ag ystyried y pryder.

Hysbysu ynghylch penderfyniadau a wneir gan Fwrdd Iechyd Lleol yn unol â rheoliadau 19 a 20

21.–(1) Os yw'r Bwrdd Iechyd Lleol yn penderfynu, yn unol â rheoliad 19(1) neu 20(1) ei fod yn briodol iddo ymdrin â phryder, rhaid iddo–

(a) hysbysu'r person a hysbysodd y pryder a'r darparwr gofal sylfaenol o'i benderfyniad; a

(b) parhau i ymdrin â'r pryder yn unol â'r Rheoliadau hyn.

(2) Os yw'r Bwrdd Iechyd Lleol yn penderfynu, yn unol â rheoliad 19(1) neu 20(1) y byddai'n fwy priodol i'r darparwr gofal sylfaenol ymdrin â'r pryder, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r person a hysbysodd y pryder a'r darparwr gofal sylfaenol o'i benderfyniad.

(3) Pan fo'r darparwr gofal sylfaenol yn cael yr hysbysiad o'r penderfyniad a ddyroddir gan y Bwrdd Iechyd Lleol o dan baragraff (2)–

(a) rhaid i'r darparwr gofal sylfaenol ymdrin â'r pryder yn unol â'r Rheoliadau hyn; a

(b) ystyrir bod y person a hysbysodd y pryder wedi hysbysu'r pryder i'r darparwr gofal

Action to be taken where a Local Health Board receives notification of a concern from a primary care provider

20.–(1) When a Local Health Board is notified of a concern by a primary care provider it must determine whether, in its opinion, the concern is appropriate for it to consider or whether it is more appropriate for the primary care provider who is the subject of the concern to consider.

(2) Before making the decision the Local Health Board must–

(a) determine whether or not the concern has been considered by the primary care provider and, if so, whether a response has been issued by the provider in accordance with regulation 24; and

(b) determine whether or not the person who notified the concern consents to the Local Health Board considering the concern if it decides in accordance with paragraph (2) that it is appropriate for it to do so.

(3) If a response has been issued by the provider in accordance with regulation 24, the Local Health Board must not consider the concern.

(4) If the person who notified the concern is unwilling to consent to the Local Health Board dealing with the concern, the Local Health Board must not consider the concern.

Communication of decisions made by a Local Health Board in accordance with regulations 19 and 20

21.–(1) If the Local Health Board decides, in accordance with regulation 19(1) or 20(1) that it is appropriate for it to deal with a concern it must–

(a) advise the person who notified the concern and the primary care provider of its decision; and

(b) continue to deal with the concern in accordance with these Regulations.

(2) If the Local Health Board decides, in accordance with regulation 19(1) or 20(1) that it is more appropriate for the concern to be dealt with by the primary care provider the Local Health Board must advise the person who notified the concern and the primary care provider of its decision.

(3) When the primary care provider receives the notification of the decision issued by the Local Health Board under paragraph (2)–

(a) the primary care provider must deal with the concern in accordance with these Regulations; and

(b) the person who notified the concern is deemed to have notified the concern to the primary care

sylfaenol yn unol â'r Rheoliadau hyn.

(4) Y terfyn amser ar gyfer hysbysu ynghylch penderfyniad a wneir o dan reoliad 19(1) neu 20(1) yw pum niwrnod gwaith ar ôl i'r Bwrdd Iechyd Lleol benderfynu'r materion a amlinellir yn rheoliad 19(2) neu 20(2).

(5) Rhaid i Fwrdd Iechyd Lleol roi rhesymau am ei benderfyniad o dan reoliad 19(1) neu 20(1).

(6) Pan fo Bwrdd Iechyd Lleol wedi cael hysbysiad o bryder gan neu ar ran person sy'n cael neu sydd wedi cael gwasanaethau gan ddarparwr gofal sylfaenol, a'r Bwrdd Iechyd Lleol wedi penderfynu y byddai'n fwy priodol i'r pryder gael ei drin gan y darparwr gofal sylfaenol sy'n destun y pryder, rhaid i'r Bwrdd Iechyd Lleol hysbysu'r person a hysbysodd y pryder o'i hawl i hysbysu pryder ynghylch penderfyniad y Bwrdd Iechyd Lleol i Ombwdsmon Gwasanaethau Cyhoeddus Cymru.

(7) Rhaid i'r Bwrdd Iechyd Lleol beidio â hysbysu'r darparwr gofal sylfaenol ei fod yn ymchwilio i bryder yn unol â'r Rheoliadau hyn pan fo rheoliad 19(4) yn gymwys.

provider in accordance with these Regulations.

(4) The time limit for notifying a decision made under regulation 19(1) or 20(1) is five working days from the date that the Local Health Board determines the matters outlined in regulation 19(2) or 20(2).

(5) A Local Health Board must give reasons for its decision under regulation 19(1) or 20(1).

(6) When a Local Health Board receives a concern notified by or on behalf of a person who is receiving or has received services from a primary care provider and the Local Health Board's decision is that it is more appropriate for the concern to be dealt with by the primary care provider who is the subject of the concern, the Local Health Board must advise the person who notified the concern of their right to notify a concern about the decision of the Local Health Board to the Public Services Ombudsman for Wales.

(7) The Local Health Board must not advise the primary care provider that it is investigating a concern in accordance with these Regulations where regulation 19(4) applies.

RHAN 5

TRIN AC YMCHWILIO I BRYDERON

Y weithdrefn cyn ymchwilio

22.–(1) Ac eithrio pan fo rheoliad 14(1)(dd) neu 18 yn gymwys, rhaid i gorff cyfrifol gydnabod ei fod wedi cael yr hysbysiad o'r pryder, ddim hwyrach na dau ddiwrnod gwaith ar ôl y diwrnod y mae'n ei gael.

(2) Caniateir cydnabod naill ai mewn ysgrifen neu'n electronig, yn ôl pa bynnag ddull a ddefnyddiwyd i hysbysu'r pryder.

(3) Os hysbyswyd y pryder ar lafar, rhaid cydnabod mewn ysgrifen.

(4) Yr un pryd ag y bo'n cydnabod yr hysbysiad o bryder, rhaid i'r corff cyfrifol gynnig trafod gyda'r person a hysbysodd y pryder, ar adeg sydd i'w chytuno gyda'r person hwnnw, y materion canlynol–

(a) y modd yr ymdrinnir ag ymchwilio i'r pryder, gan gynnwys caniatâd i ddefnyddio cofnodion meddygol;

(b) argaeledd gwasanaethau eiriolaeth a chefnogaeth, a allai fod o gymorth i'r person hwnnw wrth fwrw ymlaen â'r pryder;

(c) o fewn pa gyfnod y mae'n debygol–

(i) y cwblheir yr ymchwiliad i'r pryder; a

(ii) yr anfonir yr ymateb at y person, fel sy'n

PART 5

HANDLING AND INVESTIGATION OF CONCERNS

Procedure before investigation

22.–(1) Except where regulation 14(1)(f) or 18 applies, a responsible body must acknowledge receipt of the notification of the concern not later than two working days after the day on which it receives it.

(2) The acknowledgement may be made in writing or electronically, depending upon how the concern was notified.

(3) Where a concern was notified verbally, the acknowledgement must be in writing.

(4) At the time it acknowledges notification of a concern, the responsible body must offer to discuss with the person who notified the concern, at a time to be agreed with that person–

(a) the manner in which the investigation of the concern will be handled, including consent to the use of medical records;

(b) the availability of advocacy and support services which may be of assistance to that person in their pursuit of the concern;

(c) the period within which–

(i) the investigation of the concern is likely to be completed; and

(ii) the response required by regulation 24 is

ofynnol o dan reoliad 24.

(5) Os nad yw'r person a hysbysodd y pryder yn derbyn y cynnig o drafodaeth o dan baragraff (4), rhaid i'r corff cyfrifol ystyried a phenderfynu ar y materion a bennir yn is-baragraffau (a) i (c) o'r paragraff hwnnw, ac ysgrifennu at y person ynglŷn â hynny.

(6) Rhaid i'r corff cyfrifol anfon copi o'r hysbysiad o bryder at unrhyw berson sy'n destun y pryder hwnnw, ac eithrio–

(a) pan fo hynny wedi ei wneud eisoes; neu

(b) os byddai darparu copi o'r hysbysiad i'r cyfryw berson ar yr adeg honno, ym marn resymol y corff cyfrifol, yn rhagfarnu ystyriaeth gan y corff cyfrifol o'r materion a godir gan y pryder.

Ymchwilio i bryderon

23.–(1) Rhaid i gorff cyfrifol ymchwilio i'r materion a godir mewn hysbysiad o bryder yn y dull sy'n ymddangos i'r corff hwnnw fel y dull mwyaf priodol er mwyn dod i gasgliad ynglŷn â'r materion hynny yn drwyadl, cyflym ac effeithlon, gan roi sylw penodol i'r canlynol–

(a) cynnal asesiad dechreuol o'r pryder, a fydd yn gymorth i benderfynu ar ddyfnder a pharamedrau'r ymchwiliad a fydd yn ofynnol, a chadw'r penderfyniad hwnnw dan arolwg;

(b) dull ac amseriad y cyfathrebu â'r person a hysbysodd y pryder, neu yr effeithir arno gan y pryder;

(c) y dull mwyaf priodol o gynnwys y person a hysbysodd y pryder yn yr ymchwiliad, gan gynnwys trafodaeth ynghylch y modd y caiff yr ymchwiliad ei gynnal;

(ch) y lefel a'r math o gymorth a fydd yn ofynnol gan unrhyw aelod neu aelodau o staff y corff cyfrifol a fydd yn ymwneud â'r materion a godir gan y pryder;

(d) a fydd angen cyngor meddygol annibynnol neu gyngor annibynnol arall ar y person a fydd yn ymchwilio i'r materion a godir gan y pryder;

(dd) a yw'r pryder yn un y gellir ei ddatrys drwy ddefnyddio dull amgen o ddatrys anghydfod;

(e) gwneud penderfyniadau ynghylch achos sylfaenol y materion a arweiniodd at hysbysu'r pryder;

(f) unrhyw ganllawiau a roddir gan Weinidogion Cymru ynglŷn ag arfer swyddogaethau'r corff cyfrifol; ac

(ff) pan fo'r corff cyfrifol yn gorff GIG Cymru a'r pryder a hysbyswyd yn cynnwys honiad bod, neu y gallai fod, niwed wedi ei achosi–

likely to be sent to that person.

(5) If the person who notifies the concern does not accept the offer of a discussion under paragraph (4), the responsible body must consider and make a decision upon the matters set out in sub-paragraphs (a) to (c) of that paragraph and write to the person accordingly.

(6) The responsible body must send a copy of the notification of a concern to any person who is the subject of that concern unless–

(a) this has already been done; or

(b) provision of a copy of the notification to such a person at that time would, in the reasonable opinion of the responsible body, prejudice its consideration of the matters raised by the concern.

Investigation of concerns

23.–(1) The responsible body must investigate the matters raised in the notification of a concern in the manner which appears to that body to be most appropriate to reach a conclusion in respect of those matters thoroughly, speedily and efficiently, having particular regard to–

(a) the carrying out of an initial assessment of the concern to assist in its determination of the depth and the parameters of the investigation required and keeping this determination under review;

(b) the method and timing of communication with the person who notified or who is affected by the concern;

(c) the most appropriate method of involving the person who notified the concern with the investigation, including discussion about how the investigation is conducted;

(d) the level and type of support required by any member or members of the staff of the responsible body who are involved in the matters raised by the concern;

(e) whether the person investigating the matters raised by the concern requires independent medical or other advice;

(f) whether the concern may be capable of resolution by making use of alternative dispute resolution;

(g) the making of decisions about the root cause of the matters giving rise to the notification of the concern;

(h) any guidance issued by the Welsh Ministers with respect to the exercise of the responsible body's functions; and

(i) where the responsible body is a Welsh NHS body and the concern notified includes an allegation that harm has or may have been caused–

(i) y tebygolrwydd o unrhyw atebolrwydd cymwys;

(ii) y ddyletswydd i ystyried iawn yn unol â rheoliad 25; a

(iii) pan fo'n briodol, ystyried y gofynion ychwanegol a bennir yn Rhan 6.

(2) Pan fo pryder wedi ei hysbysu i Fwrdd Iechyd Lleol gan neu ynghylch darparwr gofal sylfaenol yn unol â rheoliad 13(1)(ch) a rheoliad 18, rhaid i'r Bwrdd Iechyd Lleol beidio ag ystyried y materion ym mharagraff (1)(ff).

Ymateb

24.–(1) Ac eithrio pan fo rheoliad 26 yn gymwys a chorff cyfrifol sy'n gorff GIG Cymru yn paratoi adroddiad interim yn unol â'r rheoliad hwnnw, rhaid i gorff cyfrifol baratoi ymateb ysgrifenedig i'r mater neu faterion a godir mewn hysbysiad o bryder a fu'n destun ymchwiliad yn unol â threfniadau ar gyfer ymdrin â phryderon o dan y Rheoliadau hyn, a rhaid i'r ymateb hwnnw–

(a) crynhoi natur a sylwedd y mater neu faterion a godwyd yn y pryder;

(b) disgrifio'r ymchwiliad a gynhaliwyd yn unol â rheoliad 23;

(c) cynnwys copïau o unrhyw farn arbenigol a gafodd y person a fu'n ymchwilio i'r pryder yn ystod yr ymchwiliad;

(ch) cynnwys copi o unrhyw gofnodion meddygol perthnasol, pan fo hynny'n briodol;

(d) pan fo'n briodol, cynnwys ymddiheuriad;

(dd) nodi sut y gweithredir, os bydd gweithredu, yng ngoleuni canlyniad yr ymchwiliad;

(e) cynnwys manylion am yr hawl i hysbysu pryder i Ombwdsmon Gwasanaethau Cyhoeddus Cymru;

(f) cynnig cyfle i'r person a hysbysodd y pryder drafod cynnwys yr ymateb gyda'r swyddog cyfrifol neu berson sy'n gweithredu ar ei ran; ac

(ff) cael ei lofnodi gan y swyddog cyfrifol neu berson sy'n gweithredu ar ei ran.

(2) Mewn perthynas â phryder sy'n cynnwys honiad bod, neu y gallai fod, niwed wedi ei achosi, rhaid i gorff cyfrifol sy'n gorff GIG Cymru, os yw o'r farn nad oes atebolrwydd cymwys, roi rhesymau am y penderfyniad hwnnw yn yr ymateb.

(3) Rhaid i gorff cyfrifol gymryd pob cam rhesymol i anfon ymateb at y person a hysbysodd y pryder o fewn cyfnod o ddeg ar hugain o ddiwrnodau gwaith sy'n cychwyn gyda'r diwrnod y cafodd yr hysbysiad o bryder.

(4) Os yw corff cyfrifol yn analluog i ddarparu ymateb o fewn deg ar hugain o ddiwrnodau gwaith yn

(i) the likelihood of any qualifying liability arising;

(ii) the duty to consider redress in accordance with regulation 25; and

(iii) where appropriate, consideration of the additional requirements set out in Part 6.

(2) Where a concern has been notified to a Local Health Board by or about a primary care provider in accordance with regulation 13(1)(d) and regulation 18, the Local Health Board must not consider the matters in paragraph (1)(i).

Response

24.–(1) Unless regulation 26 applies and a responsible body that is a Welsh NHS body produces an interim report in accordance with that regulation, a responsible body must prepare a written response to the matter or matters raised in a concern which has been investigated in accordance with arrangements for dealing with concerns under these Regulations which–

(a) summarises the nature and substance of the matter or matters raised in the concern;

(b) describes the investigation undertaken in accordance with regulation 23;

(c) contains copies of any expert opinions that the person investigating the concern has received during the investigation;

(d) contains a copy of any relevant medical records, where this is appropriate;

(e) where appropriate, contains an apology;

(f) identifies what action, if any, will be taken in light of the outcome of the investigation;

(g) contains details of the right to notify the concern to the Public Services Ombudsman for Wales;

(h) offers the person notifying the concern the opportunity to discuss the contents of the response with the responsible officer or a person acting on his or her behalf; and

(i) is signed by the responsible officer or a person acting on his or her behalf.

(2) In respect of a concern which includes an allegation that harm has or may have been caused, a responsible body that is a Welsh NHS body must, if it is of the view that there is no qualifying liability give reasons in the response for this decision.

(3) A responsible body must take all reasonable steps to send a response to the person who notified the concern within thirty working days beginning on the day upon which it received notification of the concern.

(4) If a responsible body is unable to provide a response within thirty working days in accordance with

unol â pharagraff (3), rhaid iddo–

(a) hysbysu'r person a hysbysodd y pryder o hynny, gan esbonio'r rheswm; a

(b) anfon yr ymateb cyn gynted ag y bo'n rhesymol ymarferol ac o fewn cyfnod o chwe mis sy'n cychwyn gyda'r diwrnod y cafodd y corff cyfrifol yr hysbysiad o bryder.

(5) Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o chwe mis ym mharagraff (4)(b), rhaid i'r corff cyfrifol hysbysu'r person a hysbysodd y pryder o'r rhesymau am yr oedi a pha bryd y gellir disgwyl ymateb.

paragraph (3), it must–

(a) notify the person who notified the concern accordingly and explain the reason why; and

(b) send the response as soon as reasonably practicable and within six months beginning on the day upon which it received notification of the concern.

(5) If exceptional circumstances mean that the six month period in paragraph (4)(b) cannot be adhered to, the responsible body must advise the person who notified the concern of the reasons for the delay and when a response may be expected.

RHAN 6

IAWN

Dyletswydd i ystyried iawn

25.–(1) Pan fo corff cyfrifol sy'n gorff GIG Cymru yn ymgymryd ag ymchwiliad i bryder yn unol â rheoliad 23, a'r corff GIG Cymru hwnnw yn penderfynu bod, neu y gallai fod atebolrwydd cymwys, rhaid iddo benderfynu, yn unol â darpariaethau'r Rhan hon, pa un a ddylid cynnig iawn i'r claf ai peidio.

(2) Caiff corff GIG Cymru wneud cynnig o iawn os cadarnheir, yn unol â darpariaethau'r Rheoliadau hyn, bod atebolrwydd cymwys yn bodoli.

Ymateb i ymchwiliad o dan reoliad 23 pan benderfynir bod, neu y gall fod, atebolrwydd cymwys

26.–(1) Pan fo corff GIG Cymru, ar ôl cynnal ymchwiliad o dan reoliad 23, o'r farn bod neu y gall fod, atebolrwydd cymwys, rhaid i'r corff GIG Cymru hwnnw baratoi adroddiad interim, sydd–

(a) yn crynhoi natur a sylwedd y mater neu'r materion a hysbyswyd yn y pryder;

(b) yn disgrifio'r ymchwiliad a ymgymerwyd yn unol â rheoliad 23;

(c) yn disgrifio pam, ym marn y corff GIG Cymru, y mae neu y gall fod atebolrwydd cymwys;

(ch) yn cynnwys copi o unrhyw gofnodion meddygol perthnasol;

(d) yn esbonio bod mynediad at gyngor cyfreithiol ar gael yn ddi-dâl yn unol â darpariaethau rheoliad 32;

(dd) yn esbonio bod gwasanaethau eiriolaeth a chefnogaeth ar gael, a allai fod o gymorth;

(e) yn esbonio'r weithdrefn a ddilynir er mwyn

PART 6

REDRESS

Duty to consider redress

25.–(1) Where an investigation of a concern is being undertaken in accordance with regulation 23 by a responsible body that is a Welsh NHS body and the Welsh NHS body determines that a qualifying liability exists or may exist, it must, in accordance with the provisions of this Part, determine whether or not an offer of redress should be made to the patient.

(2) An offer of redress may be made by a Welsh NHS body where it is established, in accordance with the provisions of these Regulations, that a qualifying liability exists.

Response to an investigation under regulation 23 where it is decided that there is or there may be a qualifying liability

26.–(1) Where following an investigation under regulation 23 a responsible body that is a Welsh NHS body is of the opinion that there is or there may be a qualifying liability, that Welsh NHS body must produce an interim report which–

(a) summarises the nature and substance of the matter or matters notified in the concern;

(b) describes the investigation undertaken in accordance with regulation 23;

(c) describes why, in the opinion of the Welsh NHS body, there is or there may be a qualifying liability;

(d) contains a copy of any relevant medical records;

(e) explains the availability of access to legal advice without charge in accordance with the provisions of regulation 32;

(f) explains the availability of advocacy and support services which may be of assistance;

(g) explains the procedure which will be followed

penderfynu a oes atebolrwydd cymwys yn bodoli ai peidio, a'r weithdrefn ar gyfer cynnig iawn os canfyddir bod atebolrwydd cymwys o'r fath yn bodoli;

(f) yn cadarnhau y rhoddir ar gael gopi o adroddiad yr ymchwiliad y cyfeirir ato yn rheoliad 31, pan baratoir ef, yn unol â darpariaethau'r rheoliad hwnnw i'r person sy'n ceisio iawn;

(ff) yn cynnwys manylion am yr hawl i hysbysu pryder i Ombwdsmon Gwasanaethau Cyhoeddus Cymru;

(g) yn cynnig cyfle i'r person sy'n ceisio iawn drafod cynnwys yr adroddiad interim gyda'r swyddog cyfrifol neu berson sy'n gweithredu ar ei ran; ac

(ng) wedi ei lofnodi gan y swyddog cyfrifol neu berson sy'n gweithredu ar ei ran.

(2) Ac eithrio pan fo paragraff (3) yn gymwys, rhaid i gorff GIG Cymru gymryd pob cam rhesymol i anfon adroddiad interim at y person a hysbysodd y pryder o fewn cyfnod o ddeg ar hugain o ddiwrnodau gwaith sy'n cychwyn gyda'r diwrnod y cafodd y hysbysiad o bryder.

(3) Os na all corff GIG Cymru ddarparu adroddiad interim yn unol â pharagraff (2), rhaid iddo–

(a) hysbysu'r person a hysbysodd y pryder o hynny, gan esbonio'r rheswm; a

(b) anfon yr adroddiad interim cyn gynted ag y bo'n rhesymol ymarferol ac o fewn cyfnod o chwe mis sy'n cychwyn gyda'r diwrnod y cafodd yr hysbysiad o bryder.

(4) Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o chwe mis, rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder o'r rhesymau am yr oedi a pha bryd y gellir disgwyl cael yr adroddiad interim.

(5) Rhaid darparu adroddiad yr ymchwiliad, y cyfeirir ato yn rheoliad 31, i'r person a hysbysodd y pryder neu i'w gynrychiolydd cyfreithiol cyn gynted ag y bo'n rhesymol ymarferol, a hynny ddim hwyrach na deuddeng mis ar ôl y dyddiad y cafodd y corff GIG Cymru yr hysbysiad o bryder.

(6) Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o ddeuddeng mis, rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder neu ei gynrychiolydd cyfreithiol o'r rhesymau am yr oedi a pha bryd y gellir disgwyl cael adroddiad yr ymchwiliad.

Ffurf o iawn

27.–(1) Mae iawn o dan y Rhan hon yn cynnwys–

(a) gwneud cynnig o ddigolledlad i fodloni unrhyw hawl i ddwyn achos sifil mewn

to determine whether or not a qualifying liability exists and the procedure for making an offer of redress if such a qualifying liability is found to exist;

(h) confirms that, when prepared, a copy of the investigation report referred to in regulation 31 will be made available, in accordance with the provisions of that regulation, to the person who is seeking redress;

(i) contains details of the right to notify the concern to the Public Services Ombudsman for Wales;

(j) offers the person who is seeking redress the opportunity to discuss the contents of the interim report with the responsible officer or a person acting on his or her behalf; and

(k) is signed by the responsible officer or a person acting on his or her behalf.

(2) Save where paragraph (3) applies, a Welsh NHS body must take all reasonable steps to send an interim report to the person who notified the concern within thirty working days beginning with the day on which it received notification of the concern.

(3) If a Welsh NHS body is not able to provide an interim report in accordance with paragraph (2), it must–

(a) notify the person who notified the concern accordingly and explain the reason why; and

(b) send the interim report as soon as reasonably practicable and within six months beginning with the day upon which it received notification of the concern.

(4) If exceptional circumstances mean that the six month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern of the reasons for the delay and when the interim report may be expected.

(5) The investigation report referred to in regulation 31 must be provided to the person who notified the concern or his or her legal representative as soon as reasonably practicable and not later than twelve months from the date that the Welsh NHS body received notification of the concern.

(6) If exceptional circumstances mean that the twelve month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern or his or her legal representative of the reasons for the delay and when the investigation report may be expected.

Form of redress

27.–(1) Redress under this Part comprises–

(a) the making of an offer of compensation in satisfaction of any right to bring civil

perthynas ag atebolrwydd cymwys;

(b) rhoi esboniad;

(c) gwneud ymddiheuriad ysgrifenedig; ac

(ch) rhoi adroddiad ar y modd y gweithredwyd, neu y gweithredir yn y dyfodol, i rwystro achosion cyffelyb rhag digwydd eto.

(2) Caiff yr iawn y caniateir ei gynnig yn unol â rheoliad 27(1)(a) fod ar ffurf ymuno mewn contract i ddarparu gofal neu driniaeth neu ar ffurf digolledіad ariannol, neu'r ddau.

Argaeledd iawn

28.–(1) Nid oes iawn ar gael mewn perthynas ag atebolrwydd sydd, neu a fu, yn destun achos sifil.

(2) Os cychwynnir achos sifil o'r fath yn ystod ystyriaeth o iawn gan gorff GIG Cymru, rhaid terfynu'r ystyriaeth o iawn gan y corff GIG Cymru yn unol â'r Rheoliadau hyn, a rhaid i'r Corff GIG Cymru hysbysu'r person a hysbysodd y pryder, yn unol â hynny.

Iawn – digolledіad ariannol

29.–(1) Caiff corff GIG Cymru wneud cynnig o iawn am atebolrwydd cymwys ar ffurf digolledіad ariannol pan nad yw'r swm yn fwy nag £25,000.

(2) Pan fo corff GIG Cymru o'r farn bod y gwerth sydd i'w briodoli i'r atebolrwydd cymwys yn fwy na £25,000, rhaid peidio â chynnig iawn ar ffurf digolledіad ariannol yn unol â'r Rhan hon.

(3) Os yw corff GIG Cymru, yn unol â pharagraff (2), o'r farn yr eir dros ben y terfyn ariannol a bennir gan y Rheoliadau hyn, ac os daw'r ymchwiliad a gynhelir gan y corff GIG Cymru i'r casgliad bod atebolrwydd cymwys, caiff y corff GIG Cymru ystyried gwneud cynnig o setliad y tu allan i ddarpariaethau'r Rheoliadau hyn.

(4) Cyfrifir yr iawndal am boen, dioddefaint a cholled amwynder ar sail y gyfraith gyffredin. Caiff Gweinidogion Cymru, o bryd i'w gilydd, ddyroddi tariff digolledu.

(5) Os dyroddir tariff yn unol â pharagraff (4), mae cyrff GIG Cymru i'w ddefnyddio at ddibenion canllaw wrth ystyried swm y digolledіad ariannol sydd i'w gynnig yn unol â'r Rhan hon.

Atal dros dro gyfnod y cyfyngiad

30.–(1) Yn ystod y cyfnod pan fo atebolrwydd yn destun cais am iawn o dan y Rhan hon, atelir unrhyw gyfnod cyfyngiad ar gyfer dwyn achos sifil mewn perthynas â'r atebolrwydd hwnnw, a ragnodir gan neu

proceedings in respect of a qualifying liability;

(b) the giving of an explanation;

(c) the making of a written apology; and

(d) the giving of a report on the action which has been, or will be, taken to prevent similar cases arising.

(2) The compensation that may be offered in accordance with regulation 27(1)(a) can take the form of entry into a contract to provide care or treatment or of financial compensation, or both.

Availability of Redress

28.–(1) Redress is not available in relation to a liability that is or has been the subject of civil proceedings.

(2) If such civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress in accordance with these Regulations must cease and the Welsh NHS body must advise the person who notified the concern accordingly.

Redress – financial compensation

29.–(1) A Welsh NHS body may make an offer of redress for a qualifying liability by way of financial compensation in which the sum does not exceed £25,000.

(2) Where a Welsh NHS body considers that the value to be attributed to the qualifying liability exceeds £25,000, redress in the form of financial compensation must not be offered in accordance with this Part.

(3) If, in accordance with paragraph (2), a Welsh NHS body considers that the financial limit set by these Regulations will be exceeded, if the investigation conducted by the Welsh NHS body concludes that there is a qualifying liability, the Welsh NHS body may give consideration to making an offer of settlement outside the provisions of these Regulations.

(4) The assessment of damages for pain, suffering and loss of amenity is calculated on the common law basis. Welsh Ministers may from time to time issue a compensation tariff.

(5) If a tariff is issued in accordance with paragraph (4), it is to be used for the purpose of guidance by Welsh NHS bodies when considering the amount of financial compensation to be offered in accordance with this Part.

Suspension of the limitation period

30.–(1) During the period in which a liability is the subject of an application for redress under this Part, any limitation period for the bringing of civil proceedings in respect of that liability which is

o dan Ddeddf Cyfyngiadau 1980(**1**) neu unrhyw ddeddfiad arall, ac ni fydd amser yn treiglo at ddibenion cyfrifo unrhyw derfynau amser a ragnodir gan y deddfiadau hynny.

(2) At ddibenion y Rhan hon, ystyrir bod atebolrwydd yn destun cais am iawn am gyfnod–

(a) sy'n cychwyn gyda'r dyddiad y cafodd y corff GIG Cymru yr hysbysiad o bryder dechreuol a ddaeth yn gais am iawn; a

(b) yn ddarostyngedig i baragraffau (3), (4) a (5), sy'n parhau hyd at, a chan gynnwys, y dyddiad y mae'r claf neu ei gynrychiolydd yn derbyn cynnig o ddigolllediad ariannol a wnaed yn unol â rheoliad 33 drwy lofnodi cytundeb ffurfiol ac ildiad cyfreithiol yn unol â rheoliad 33(d), neu hyd nes bo'r claf neu ei gynrychiolydd yn gwrthod cynnig o ddigolledliad o'r fath.

(3) Nid ystyrir mwyach bod atebolrwydd yn destun cais am iawn ymhen naw mis calendr o'r dyddiad pan wneir cynnig o ddigolledliad ariannol gan y corff GIG Cymru mewn perthynas â'r atebolrwydd hwnnw.

(4) Mewn achosion pan fo cymeradwyaeth llys yn ofynnol ar gyfer setliad a gynigir, megis yn yr amgylchiadau a amlinellir yn rheoliad 33(dd), os bydd cyfyngiad amser yn fater perthnasol, atelir cyfnod y cyfyngiad dros dro, tan y dyddiad y cymeradwyir y setliad gan y llys.

(5) Mewn achosion pan fo corff GIG Cymru yn dynodi, yn unol â rheoliad 33, ei fod o'r farn nad oes atebolrwydd cymwys, ac wedi penderfynu peidio â gwneud cynnig o iawn, nid ystyrir mwyach bod atebolrwydd yn destun cais am iawn ymhen naw mis calendr o'r dyddiad y rhoddodd y corff GIG Cymru hysbysiad o'i benderfyniad yn unol â rheoliad 33.

Adroddiad yr ymchwiliad

31.–(1) Rhaid i gorff GIG Cymru sicrhau bod canfyddiadau'r ymchwiliad i bryder, pan fo person yn ceisio iawn o dan y Rhan hon, yn cael eu cofnodi mewn adroddiad ar yr ymchwiliad.

(2) Rhaid i adroddiad ar ymchwiliad gynnwys y canlynol–

(a) copi o unrhyw dystiolaeth feddygol a gomisiynwyd yn unol â'r Rhan hon er mwyn penderfynu a oes atebolrwydd cymwys ai peidio, neu a gomisiynwyd i ganfod cyflwr a phrognosis;

(b) hysbysiad gan y corff GIG Cymru yn cadarnhau a oes, yn ei farn ef, atebolrwydd cymwys ai peidio; ac

(**1**) 1980 p.58.

prescribed by or under the Limitation Act 1980(**1**) or any other enactment is suspended and time will not run for the purposes of calculating any time limits prescribed by these enactments.

(2) For the purposes of this Part, a liability is to be considered as being the subject of an application for redress–

(a) for the period beginning with the date on which the initial concern which became an application for redress was received by a Welsh NHS body; and

(b) subject to paragraphs (3), (4) and (5), up to and including the date when an offer of financial compensation made in accordance with regulation 33 is accepted by a patient or his or her representative by signing a formal agreement and legal waiver in accordance with regulation 33(e) or until such time as an offer of such compensation is rejected by a patient or his or her representative.

(3) A liability will no longer be considered as being the subject of an application for redress nine calendar months from the date upon which the Welsh NHS body makes an offer of financial compensation in respect of that liability.

(4) In cases where court approval of a settlement proposed by an offer is required, such as in circumstances outlined in regulation 33(f), limitation, if limitation is an issue, is suspended until the date upon which the court approves the settlement.

(5) In cases where a Welsh NHS body indicates, in accordance with regulation 33, that it is of the opinion that there is no qualifying liability and has decided not to make an offer of redress, a liability will not be considered to be the subject of an application for redress nine calendar months from the date on which the Welsh NHS body communicated its decision in accordance with regulation 33.

Investigation report

31.–(1) A Welsh NHS body must ensure that the findings of the investigation of a concern in which a person is seeking redress under this Part are recorded in an investigation report.

(2) An investigation report must contain the following–

(a) a copy of any medical evidence that has been commissioned in accordance with this Part in order to determine whether or not there is a qualifying liability or which has been commissioned to determine condition and prognosis;

(b) a statement by the Welsh NHS body confirming whether or not, in its opinion, there is a qualifying liability; and

(**1**) 1980 c.58.

(c) esboniad o'r farn a fynegir yn is-baragraff (b).

(3) Ac eithrio pan fo paragraff (4) yn gymwys, rhaid i'r corff GIG Cymru ddarparu copi o adroddiad yr ymchwiliad i'r person sy'n ceisio iawn o dan y Rhan hon, neu ei gynrychiolydd, o fewn y terfyn amser a bennir yn rheoliad 26(5) a (6).

(4) Nid oes angen i'r corff GIG Cymru ddarparu copi o adroddiad yr ymchwiliad–

(a) cyn gwneud cynnig o iawn o dan y Rhan hon;

(b) cyn rhoi hysbysiad o'i benderfyniad i beidio â gwneud cynnig o iawn;

(c) os terfynir, am unrhyw reswm, yr ymchwiliad i'r iawn yn unol â'r Rhan hon; neu

(ch) pan fo'r adroddiad yn cynnwys gwybodaeth sy'n debygol o beri niwed neu drallod sylweddol i'r claf neu i geisydd arall am iawn.

Cyngor cyfreithiol a chyfarwyddo arbenigwyr meddygol

32.–(1) Pan fo corff GIG Cymru wedi penderfynu, yn unol â rheoliad 26 a'r Rhan hon, bod, neu y gall fod, atebolrwydd cymwys, rhaid i'r corff GIG Cymru sicrhau–

(a) bod cyngor cyfreithiol ar gael i berson sy'n ceisio iawn o dan y Rhan hon, yn unol â darpariaethau canlynol y rheoliad hwn; a

(b) os oes angen cyfarwyddo arbenigwr neu arbenigwyr meddygol, y cyflawnir y cyfarwyddo ar y cyd gan y corff GIG Cymru a'r person a hysbysodd y pryder yn unol â rheoliad 11.

(2) Rhaid ceisio cyngor cyfreithiol gan y ffyrmiau cyfreithwyr hynny, yn unig, sydd ag arbenigedd cydnabyddedig ym maes esgeuluster clinigol. Cydnabyddir bod gan ffyrmiau yr arbenigedd angenrheidiol os oes ganddynt o leiaf un partner neu gyflogai sy'n aelod o Banel Esgeuluster Clinigol Cymdeithas y Cyfreithwyr(1) neu Weithredu yn erbyn

(1) Mae Cymdeithas y Cyfreithwyr yn rhedeg cynllun achredu ar gyfer cyfreithwyr a Chymrodyr Sefydliad y Gweithredwyr Cyfreithiol (ILEX) sy'n arbenigo mewn achosion o esgeuluster clinigol. Mae gan gyfreithwyr a Chymrodyr ILEX hawl i gael eu rhestru fel aelodau o Banel Esgeuluster Clinigol Cymdeithas y Cyfreithwyr os ydynt yn gallu dangos, yn unol â gweithdrefn gyhoeddedig Cymdeithas y Cyfreithwyr, fod ganddynt ddigon o arbenigedd mewn materion esgeuluster clinigol.

(c) an explanation for the opinion expressed in sub-paragraph (b).

(3) Unless paragraph (4) applies, the Welsh NHS body must provide the person who is seeking redress under this Part, or his or her legal representative, with a copy of the investigation report within the time frame set out in regulation 26(5) and (6).

(4) No copy of the investigation report need be provided by the Welsh NHS body–

(a) before an offer of redress under this Part is made;

(b) before a decision not to make an offer of redress is communicated;

(c) if the investigation of redress in accordance with this Part is for any reason terminated; or

(d) where the report contains information likely to cause the patient or other applicant for redress significant harm or distress.

Legal advice and instruction of medical experts

32.–(1) Where a Welsh NHS body has determined that a qualifying liability exists, or may exist, in accordance with regulation 26 and this Part, the Welsh NHS body must ensure–

(a) that legal advice is available to a person seeking redress under this Part in accordance with the following provisions of this regulation; and

(b) if a medical expert or experts need to be instructed that such instruction is carried out jointly by the Welsh NHS body and the person who has notified the concern in accordance with regulation 11.

(2) Legal advice must only be sought from firms of solicitors who have a recognised expertise in the field of clinical negligence. Firms will be recognised as having the necessary expertise if they have at least one partner or employee who is a member of the Law Society Clinical Negligence Panel (1) or the Action Against Medical Accidents Clinical Negligence Panel

(1) The Law Society runs an accreditation scheme for solicitors and Fellows of the Institute of Legal Executives (FILEX) who specialise in clinical negligence cases. Solicitors and FILEX who are able to demonstrate, in accordance with the Law Society's published procedure, that they are sufficiently expert in clinical negligence matters are eligible to be listed as a member of the Law Society Clinical Negligence Panel.

Damweiniau Meyddgol(**1**).

(3) Rhaid i gorff GIG Cymru sicrhau y bydd cyngor cyfreithiol di-dâl ar gael i'r person a hysbysodd y pryder mewn perthynas ag–

(a) cyfarwyddo arbenigwyr meddygol ar y cyd, gan gynnwys ceisio eglurhad gan y cyfryw arbenigwyr ar faterion sy'n codi o'u hadroddiadau;

(b) unrhyw gynnig a wneir yn unol â'r Rhan hon;

(c) unrhyw wrthodiad i wneud cynnig o'r fath; ac

(ch) unrhyw gytundeb setlo a gynigir.

(4) Rhaid i gost y cyfryw gyngor cyfreithiol a chostau sy'n codi o gyfarwyddo'r cyfryw arbenigwyr meddygol gael eu dwyn yn gyfan gwbl gan y corff GIG Cymru.

Iawn – hysbysu ynghylch penderfyniad

33. Pan fo corff GIG Cymru yn penderfynu gwneud cynnig o iawn ar ffurf digolledіad ariannol neu ymuno mewn contract i ddarparu gofal neu driniaeth, neu'r ddau, neu'n penderfynu peidio â gwneud cynnig o iawn, ar y sail nad oes atebolrwydd cymwys, rhaid iddo–

(a) anfon y cynnig, neu'r hysbysiad o'r penderfyniad i beidio â gwneud cynnig, at y person a hysbysodd y pryder o fewn deuddeng mis o'r dyddiad yr hysbyswyd y pryder i'r corff GIG Cymru. Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o ddeuddeng mis, rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder neu ei gynrychiolydd cyfreithiol o'r rhesymau am yr oedi a pha bryd y gwneir penderfyniad ynglŷn â'r cais am iawn;

(b) hysbysu'r person hwnnw neu ei gynrychiolydd cyfreithiol bod rhaid iddo ymateb i'r cynnig o setliad neu'r penderfyniad i beidio â gwneud cynnig o setliad o fewn chwe mis o'r dyddiad y'i hysbysir o'r cynnig neu'r penderfyniad;

(c) yn ddarostyngedig i baragraff (ch), rhoi gwybod, os na fydd yn bosibl, oherwydd amgylchiadau eithriadol, ymateb i'r cynnig o setliad neu'r penderfyniad i beidio â gwneud cynnig o setliad, o fewn chwe mis o ddyddiad y cynnig neu'r penderfyniad i beidio â gwneud cynnig, y bydd rhaid i'r person a hysbysodd y pryder neu ei gynrychiolydd cyfreithiol

(**1**).

(3) A Welsh NHS body must ensure that legal advice without charge is available to the person who notified the concern in relation to–

(a) the joint instruction of medical experts, including the seeking of clarification from such experts of issues arising from their reports;

(b) any offer that is made in accordance with this Part;

(c) any refusal to make such an offer; and

(d) any settlement agreement that is proposed.

(4) The cost of such legal advice and costs arising from the instruction of such medical experts must be borne in their entirety by the Welsh NHS body.

Redress – communication of a decision

33. Where a Welsh NHS body decides to make an offer of redress by way of financial compensation or entry into a contract to provide care or treatment or both or determines that it will not make an offer of redress on the basis that there is no qualifying liability, it must–

(a) send the offer, or the notification of the decision not to make an offer, to the person who notified the concern within twelve months of the date on which the concern was notified to the Welsh NHS body. If exceptional circumstances mean that the twelve month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern, or his or her, legal representative, of the reasons for the delay and when a decision in respect of the application for redress will be made;

(b) advise that person or his or her legal representative that he or she must respond to the offer of settlement or a decision not to make an offer of settlement within six months of the date that it is notified;

(c) subject to paragraph (d), advise that if, as a result of exceptional circumstances, it will not be possible to respond to the offer of settlement, or the decision not to make an offer of settlement, within six months of the date of the offer or decision not to make an offer, the Welsh NHS body must be advised by the person who notified the concern or his or her legal representative of the reasons for the delay

(**1**) Elusen yw Gweithredu yn erbyn Damweiniau Meddygol (AVMA) a sefydlwyd i hybu diogelwch cleifion. Mae'n rhedeg cynllun achredu ar gyfer cyfreithwyr a Chymrodyr Sefydliad y Gweithredwyr Cyfreithiol (ILEX). Gall cyfreithwyr a Chymrodyr ILEX sy'n gallu dangos eu bod yn bodloni meini prawf cyhoeddedig ar gyfer dangos arbenigedd ym maes esgeuluster clinigol ddod yn aelodau o Banel Esgeuluster Clinigol AVMA.

(**1**) Action Against Medical Accidents (AVMA) is a charity established to promote patient safety. It runs an accreditation scheme for solicitors and Fellows of the Institute of Legal Executives (FILEX). Solicitors and FILEX who can demonstrate that they meet AVMA's published criteria for demonstrating expertise in the field of clinical negligence can become members of AVMA's Clinical Negligence Panel.

hysbysu'r corff GIG Cymru o'r rhesymau am oedi'r ymateb, a pha bryd y cyflwynir ymateb;

(ch) rhoi gwybod i berson neu ei gynrychiolydd cyfreithiol, os gofynnir am estyn yr amser a ganiateir i ymateb i gynnig o setliad neu benderfyniad i beidio â gwneud cynnig o setliad, y bydd yn ofynnol ymateb o fewn naw mis calendr o ddyddiad y cynnig neu'r penderfyniad, gan mai'r dyddiad hwnnw, yn unol â rheoliad 30(3) a (5) yw dyddiad cychwyn cyfnod y cyfyngiad;

(d) rhoi gwybod, os gwneir cynnig, y bydd y setliad a gynigir ar ffurf cytundeb ffurfiol, ac y bydd rhaid i'r cytundeb gynnwys ildiad o unrhyw hawl i ddwyn achos sifil mewn perthynas â'r atebolrwydd cymwys y mae'r setliad yn ymwneud ag ef;

(dd) rhoi gwybod, mewn amgylchiadau priodol, y bydd y cytundeb setlo a gynigir yn ddarostyngedig i'w gymeradwyo gan lys, megis mewn achosion pan fo'r person y mae'r atebolrwydd cymwys yn ymwneud ag ef–

(i) yn blentyn; neu

(ii) heb alluedd yn yr ystyr a roddir i "capacity" yn Neddf Galluedd Meddyliol 2005(**1**); ac

(e) rhoi gwybod, os yw'n ofynnol cael cymeradwyaeth llys ar gyfer setliad, y bydd rhaid i'r corff GIG Cymru dalu'r costau cyfreithiol rhesymol a fydd yn gysylltiedig â chael y cyfryw gymeradwyaeth.

in responding and when a response will be submitted;

(d) advise a person or his or her legal representative that if an extension of time is sought to respond to an offer of settlement or a decision not to make an offer of settlement, a response is required within nine calendar months of the date of the offer or decision as that is the time when, in accordance with regulation 30(3) and (5), limitation starts to run;

(e) advise, if an offer is made, that the settlement proposed by the offer will be by way of a formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates;

(f) advise that, in appropriate circumstances, the settlement agreement proposed will be subject to approval by a court in cases such as those where the person to whom the qualifying liability relates–

(i) is a child; or

(ii) lacks capacity within the meaning of the Mental Capacity Act 2005(**1**); and

(g) advise that where court approval of a settlement is required, that the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

RHAN 7

GOFYNIAD AR GYRFF GIG, AC EITHRIO CYRFF GIG CYMRU, I YSTYRIED IAWN, A'R WEITHDREFN SYDD I'W DILYN GAN GORFF GIG CYMRU PAN GAIFF HYSBYSIAD O BRYDER YN UNOL Â DARPARIAETHAU'R RHAN HON

Dehongli'r Rhan hon

34.–(1) At ddibenion y Rhan hon, ystyr "corff GIG Lloegr" ("*an English NHS body*") yw–

(a) Awdurdod Iechyd Strategol, a sefydlwyd o dan adran 13 o Ddeddf y Gwasanaeth Iechyd Gwladol 2006(**2**);

(b) Ymddiriedolaeth Gofal Sylfaenol, a sefydlwyd o dan adran 18 o Ddeddf y Gwasanaeth Iechyd Gwladol 2006;

PART 7

REQUIREMENT FOR NHS BODIES, OTHER THAN WELSH NHS BODIES, TO CONSIDER REDRESS AND PROCEDURE TO BE FOLLOWED BY A WELSH NHS BODY WHEN IT RECEIVES NOTIFICATION OF A CONCERN IN ACCORDANCE WITH THE PROVISIONS OF THIS PART

Interpretation of this Part

34.–(1) For the purposes of this Part, "an English NHS body" ("*corff GIG Lloegr*") means–

(a) a Strategic Health Authority, established under section 13 of the National Health Service Act 2006(**2**);

(b) a Primary Care Trust, established under section 18 of the National Health Service Act 2006;

(**1**) 2005 p.9.

(**2**) 2006 p.41.

(**1**) 2005 c.9.

(**2**) 2006 c.41.

(c) Ymddiriedolaeth GIG, a sefydlwyd o dan adran 25 o Ddeddf y Gwasanaeth Iechyd Gwladol 2006;

(ch) Awdurdod Iechyd Arbennig, a sefydlwyd o dan adran 28 o Ddeddf y Gwasanaeth Iechyd Gwladol 2006; neu

(d) Ymddiriedolaeth Sefydledig GIG a awdurdodwyd o dan Bennod 5 o Ddeddf y Gwasanaeth Iechyd Gwladol 2006,

sy'n darparu, neu'n trefnu ar gyfer darparu, gwasanaethau y mae eu darparu yn destun trefniadau gyda chorff GIG Cymru.

(2) At ddibenion y Rhan hon, ystyr "corff GIG yr Alban" ("*a Scottish NHS body*") yw–

(a) Bwrdd Iechyd a gyfansoddwyd o dan adran 2(1)(a) o Ddeddf y Gwasanaeth Iechyd Gwladol (yr Alban) 1978(**1**);

(b) Bwrdd Iechyd Arbennig a gyfansoddwyd o dan adran 2(1)(b) o Ddeddf y Gwasanaeth Iechyd Gwladol (yr Alban) 1978; neu

(c) yr Asiantaeth Gwasanaethau Cyffredin a gyfansoddwyd o dan adran 10 o Ddeddf y Gwasanaeth Iechyd Gwladol (yr Alban) 1978,

sy'n darparu, neu'n trefnu ar gyfer darparu, gwasanaethau y mae eu darparu yn destun trefniadau gyda chorff GIG Cymru.

(3) At ddibenion y Rhan hon, ystyr "corff GIG Gogledd Iwerddon" ("*a Northern Irish NHS body*") yw–

(a) Ymddiriedolaeth Iechyd a Gwasanaethau Cymdeithasol a sefydlwyd o dan Orchymyn Iechyd a Gwasanaethau Cymdeithasol Personol (Gogledd Iwerddon) 1991(**2**);

(b) Y Bwrdd Iechyd a Gofal Cymdeithasol Rhanbarthol a sefydlwyd o dan Ddeddf Iechyd a Gofal Cymdeithasol (Diwygio) (Gogledd Iwerddon) 2009(**3**);

(c) Gwasanaeth Trallwyso Gwaed Gogledd Iwerddon a sefydlwyd o dan Orchymyn Iechyd a Gwasanaethau Cymdeithasol Personol (Asiantaethau Arbennig) 1990(**4**);

(ch) Y Sefydliad Gwasanaethau Busnes Rhanbarthol a sefydlwyd o dan Ddeddf Iechyd a Gofal Cymdeithasol (Diwygio) (Gogledd Iwerddon) 2009; neu

(d) Yr Asiantaeth Ranbarthol dros Iechyd y Cyhoedd a Lles Cymdeithasol a sefydlwyd o dan Ddeddf Iechyd a Gofal Cymdeithasol (Diwygio) (Gogledd Iwerddon) 2009,

(**1**) 1978 c.29.

(**2**) O.S.1991/194 (G.I. 1).

(**3**) 2009 p.1

(**4**) O.S. 1990/247 (G.I. 3).

(c) an NHS Trust, established under section 25 of the National Health Service Act 2006;

(d) a Special Health Authority, established under section 28 of the National Health Service Act 2006; or

(e) an NHS Foundation Trust authorised under Chapter 5 of the National Health Service Act 2006,

that is providing, or arranging for the provision of, services whose provision is the subject of arrangements with a Welsh NHS body.

(2) For the purposes of this Part, "a Scottish NHS body" ("*corff GIG yr Alban*") means–

(a) a Health Board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978(**1**);

(b) a Special Health Board constituted under section 2(1)(b) of the National Health Service (Scotland) Act 1978; or

(c) the Common Services Agency constituted under section 10 of the National Health Service (Scotland) Act 1978,

providing, or arranging for the provision of services whose provision is the subject of arrangements with a Welsh NHS body.

(3) For the purposes of this Part, "a Northern Irish NHS body" ("*corff GIG Gogledd Iwerddon*") means–

(a) a Health and Social Services Trust established under the Health and Personal Social Services (Northern Ireland) Order 1991(**2**);

(b) the Regional Health and Social Care Board established under the Health and Social Care (Reform) Act (Northern Ireland) 2009(**3**);

(c) the Northern Ireland Blood Transfusion Service established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990(**4**);

(d) the Regional Business Services Organisation established under the Health and Social Care (Reform) Act (Northern Ireland) 2009; or

(e) the Regional Agency for Public Health and Social Well-Being established under the Health and Social Care (Reform) Act (Northern Ireland) 2009,

(**1**) 1978 c.29.

(**2**) S.I. 1991/194 (N.I.1).

(**3**) 2009 c.1.

(**4**) S.I. 1990/247 (N.I. 3).

sy'n darparu neu'n trefnu ar gyfer darparu, gwasanaethau, y mae eu darparu yn destun trefniadau gyda chorff GIG Cymru.

(4) Ystyr "gweithdrefn gwynion berthnasol" ("*relevant complaints procedure*") yw gweithdrefn gwynion y mae'n rhaid i gorff GIG Lloegr ei dilyn ar ôl cael hysbysiad o bryder.

(5) Ystyr "person a hysbysodd bryder" ("*person who notified a concern*") yw, yn ôl y cyd-destun, y person a hysbysodd bryder i gorff GIG Lloegr, corff GIG yr Alban neu gorff GIG Gogledd Iwerddon.

Amgylchiadau pan fo rhaid i gorff GIG Lloegr ystyried a allai iawn fod yn gymwys ai peidio

35. Pan fo corff GIG Lloegr yn cael, o dan weithdrefn gwynion berthnasol, hysbysiad o bryder sy'n cynnwys honiad bod, neu y gallai fod, niwed wedi ei achosi, ac sy'n ymwneud â gwasanaethau a ddarparwyd ganddo neu y trefnodd i'w darparu o dan drefniadau gyda chorff GIG Cymru, rhaid i'r corff GIG Lloegr, wrth ystyried y pryder yn unol â'r weithdrefn gwynion honno, ystyried a yw'r pryder yn cynnwys atebolrwydd cymwys ai peidio, y gallai fod iawn ar gael amdano.

Camau sydd i'w cymryd pan fo corff GIG Lloegr o'r farn bod, neu y gallai fod, atebolrwydd cymwys

36.–(1) Os daw corff GIG Lloegr i'r casgliad bod, neu y gallai fod, atebolrwydd cymwys ac y gallai fod iawn ar gael, rhaid i'r corff GIG Lloegr hwnnw, cyn gynted ag y bo'n rhesymol bosibl, gymryd y camau a amlinellir ym mharagraff (2).

(2) Rhaid i'r corff GIG Lloegr hysbysu'r corff GIG Cymru yr ymunodd mewn trefniant gydag ef, ei fod o'r farn bod atebolrwydd cymwys naill ai'n bodoli, neu y gallai fodoli, ac, ar ôl sicrhau unrhyw ganiatadau priodol, darparu'r canlynol i'r corff GIG Cymru:

(a) copi o'r ymateb i unrhyw bryder, a ddarparwyd yn unol â gweithdrefn gwynion berthnasol;

(b) copi o unrhyw gofnodion meddygol perthnasol;

(c) copi o unrhyw farn arbenigol a gafwyd yn ystod yr ymchwiliad i bryder;

(ch) adroddiad ysgrifenedig pam y mae o'r farn bod, neu y gallai fod, atebolrwydd cymwys;

(d) y dyddiad y cafodd y hysbysiad o bryder; ac

(dd) pa bynnag wybodaeth neu gymorth arall y gofynnir amdani neu amdano'n rhesymol gan y corff GIG Cymru.

providing or arranging for the provision of services whose provision is the subject of arrangements with a Welsh NHS body.

(4) "Relevant complaints procedure" ("*gweithdrefn gwynion berthnasol*") means a complaints procedure that an English NHS body must follow on receipt of a concern.

(5) "Person who notified a concern" ("*person a ddatganodd bryder*") means, depending on the context, the person who notified a concern to an English NHS body, a Scottish NHS body or a Northern Irish NHS body.

Circumstances in which an English NHS body must consider whether or not redress may apply

35. If an English NHS body receives notification of a concern which includes an allegation that harm has or may have been caused under a relevant complaints procedure that relates to services which it has provided, or arranged for the provision of, under arrangements with a Welsh NHS body, that English NHS body must, when considering the concern in accordance with that complaints procedure, give consideration to whether or not the concern involves a qualifying liability for which redress may be available.

Steps to be taken where an English NHS body considers that a qualifying liability exists or may exist

36.–(1) If an English NHS body concludes that such a qualifying liability exists or may exist and that redress may be available, that English NHS body must, as soon as reasonably possible, take the steps outlined in paragraph (2).

(2) The English NHS body must notify the Welsh NHS body with whom it has entered into an arrangement that it is of the view that a qualifying liability exists or may exist and, after securing any appropriate consents, provide the Welsh NHS body with the following:

(a) a copy of the response to any concern provided in accordance with a relevant complaints procedure;

(b) a copy of any relevant medical records;

(c) a copy of any expert opinion that has been obtained during the investigation of a concern;

(d) a written account of why it believes that there is or there may be a qualifying liability;

(e) the date that it received the concern; and

(f) such other information or assistance as the Welsh NHS body may reasonably require.

Camau sydd i'w cymryd gan gorff GIG Cymru ar ôl cael hysbysiad gan gorff GIG Lloegr yn unol â rheoliad 36

37.–(1) Rhaid i gorff GIG Cymru, o fewn pum niwrnod gwaith, gydnabod derbyn yr hysbysiad a roddwyd yn unol â rheoliad 36.

(2) Rhaid iddo hefyd, o fewn pum niwrnod gwaith ar ôl cael yr hysbysiad, roi gwybod i'r person a hysbysodd y pryder i'r corff GIG Lloegr, fod y pryder bellach wedi ei anfon ato i ystyried pa un a oes atebolrwydd cymwys ai peidio.

(3) Rhaid i gorff GIG Cymru benderfynu a oes atebolrwydd cymwys ai peidio, a rhaid iddo benderfynu a ddylid gwneud cynnig o iawn i'r claf ai peidio.

Camau sydd i'w cymryd gan gorff GIG Cymru ar ôl cael hysbysiad gan gorff GIG yr Alban neu gorff GIG Gogledd Iwerddon

38.–(1) Rhaid i gorff GIG Cymru, o fewn pum niwrnod gwaith ar ôl cael yr hysbysiad oddi wrth gorff GIG yr Alban neu gorff GIG Gogledd Iwerddon, gydnabod derbyn yr hysbysiad.

(2) Rhaid iddo hefyd, o fewn pum niwrnod gwaith ar ôl cael yr hysbysiad, roi gwybod i'r person a hysbysodd y pryder, fod y pryder bellach wedi ei anfon ato i ystyried pa un a oes atebolrwydd cymwys ai peidio.

(3) Rhaid i gorff GIG Cymru benderfynu a oes atebolrwydd cymwys ai peidio, a rhaid iddo benderfynu a ddylid gwneud cynnig o iawn i'r claf ai peidio.

Dyletswydd ar gorff GIG Cymru i gynnal ymchwiliad

39.–(1) Ar ôl cael hysbysiad gan gorff GIG Lloegr, corff GIG yr Alban neu gorff GIG Gogledd Iwerddon, rhaid i gorff GIG Cymru–

(a) cynnig cyfarfod â'r person a hysbysodd y pryder; a

(b) cynnal ymchwiliad sy'n dilyn yr egwyddorion yn rheoliad 23(1)(a), (b), (c), (d), ac (f).

(2) Ar ôl cael hysbysiad gan gorff GIG Lloegr, rhaid i gorff GIG Cymru a'r corff GIG Lloegr gydweithio mewn ffordd sy'n bodloni gofynion perthnasol y Rhan hon–

(a) i benderfynu a oes atebolrwydd cymwys yn bodoli ai peidio; a

(b) os penderfynir bod atebolrwydd cymwys yn bodoli, gynnig iawn.

Action to be taken by a Welsh NHS body on receipt of a notification from an English NHS body in accordance with regulation 36

37.–(1) A Welsh NHS body must within five working days acknowledge receipt of the notification made in accordance with regulation 36.

(2) It must also, within five working days of receipt of the notification, advise the person who notified the concern to the English NHS body that the concern has been passed to it to consider whether or not a qualifying liability exists.

(3) A Welsh NHS body must determine whether or not a qualifying liability exists and it must determine whether or not an offer of redress should be made to the patient.

Action to be taken by a Welsh NHS body on receipt of a notification from a Scottish NHS body or a Northern Irish NHS body

38.–(1) A Welsh NHS body must, within five working days of receipt of a notification from a Scottish NHS body or a Northern Irish NHS body acknowledge receipt of the notification.

(2) It must also, within five working days of receipt of the notification, advise the person who notified the concern that the concern has been passed to it to consider whether or not a qualifying liability exists.

(3) A Welsh NHS body must determine whether or not a qualifying liability exists and it must determine whether or not an offer of redress should be made to the patient.

Duty of Welsh NHS body to conduct an investigation

39.–(1) On receipt of a notification from an English NHS body, a Scottish NHS body or a Northern Irish NHS body, a Welsh NHS body must–

(a) offer to meet with the person who notified the concern; and

(b) undertake an investigation that follows the principles in regulation 23(1)(a), (b), (c), (e), and (h).

(2) On receipt of a notification from an English NHS body, a Welsh NHS body and the English NHS body must co-operate, in a way which satisfies the relevant requirements of this Part–

(a) to determine whether or not a qualifying liability exists; and

(b) if it is determined that a qualifying liability exists, to make an offer of redress.

Ymateb i ymchwiliad o dan reoliad 39 pan fo corff GIG Cymru o'r farn bod, neu y gall fod, atebolrwydd cymwys

40.–(1) Pan fo corff GIG Cymru, yn dilyn ymchwiliad o dan reoliad 39, o'r farn bod, neu y gall fod, atebolrwydd cymwys, rhaid i'r corff GIG Cymru baratoi adroddiad interim, sydd–

(a) yn crynhoi natur a sylwedd y mater neu'r materion a hysbyswyd yn y pryder;

(b) yn disgrifio'r ymchwiliad a ymgymerwyd yn unol â rheoliad 39;

(c) yn disgrifio pam, ym marn y corff GIG Cymru, y mae neu y gall fod atebolrwydd cymwys;

(ch) yn cynnwys copi o unrhyw gofnodion meddygol perthnasol;

(d) yn esbonio bod mynediad at gyngor cyfreithiol ar gael yn ddi–dâl yn unol â darpariaethau rheoliad 47;

(dd) yn esbonio bod gwasanaethau eiriolaeth a chefnogaeth ar gael, a allai fod o gymorth;

(e) yn esbonio'r weithdrefn a ddilynir er mwyn penderfynu a oes atebolrwydd cymwys yn bodoli ai peidio, a'r weithdrefn ar gyfer cynnig iawn os canfyddir bod atebolrwydd cymwys o'r fath yn bodoli;

(f) yn cadarnhau y rhoddir ar gael gopi o adroddiad yr ymchwiliad y cyfeirir ato yn rheoliad 46, pan baratoir ef, yn unol â darpariaethau'r rheoliad hwnnw i'r person sy'n ceisio iawn neu i'w gynrychiolydd cyfreithiol;

(ff) yn cynnwys manylion am yr hawl i hysbysu'r pryder, mewn perthynas â gweithredoedd neu anweithiau'r corff GIG Cymru, i Ombwdsmon Gwasanaethau Cyhoeddus Cymru;

(g) yn cynnig cyfle i'r person sy'n ceisio iawn drafod cynnwys yr adroddiad interim gyda'r swyddog cyfrifol a ddynodwyd yn unol â rheoliad 7 neu berson sy'n gweithredu ar ei ran; ac

(ng) wedi ei lofnodi gan y swyddog cyfrifol neu berson sy'n gweithredu ar ei ran.

(2) Ac eithrio pan fo paragraff (3) yn gymwys, rhaid i gorff GIG Cymru gymryd pob cam rhesymol i anfon adroddiad interim at y person a hysbysodd y pryder o fewn cyfnod o hanner can niwrnod gwaith sy'n dechrau gyda'r diwrnod y cafodd y corff yr hysbysiad o bryder.

(3) Os na all corff GIG Cymru ddarparu adroddiad interim yn unol â pharagraff (2), rhaid iddo–

(a) hysbysu'r person a hysbysodd y pryder o hynny, gan esbonio'r rheswm; a

(b) anfon yr adroddiad interim cyn gynted ag y bo'n rhesymol ymarferol ac o fewn cyfnod o

Response to an investigation under regulation 39 where a Welsh NHS body is of the opinion that there is, or there may be, a qualifying liability

40.–(1) Where following an investigation under regulation 39 a Welsh NHS body considers that there is or there may be a qualifying liability it must produce an interim report which–

(a) summarises the nature and substance of the matter or matters notified in the concern;

(b) describes the investigation undertaken in accordance with regulation 39;

(c) describes why, in the opinion of the Welsh NHS body, there is or there may be a qualifying liability;

(d) contains a copy of any relevant medical records;

(e) explains the availability of access to legal advice without charge in accordance with the provisions of regulation 47;

(f) explains the availability of advocacy and support services which may be of assistance;

(g) explains the procedure which will be followed to determine whether or not a qualifying liability exists and the procedure for making an offer of redress if such a qualifying liability is found to exist;

(h) confirms that, when prepared, a copy of the investigation report referred to in regulation 46 will be made available, in accordance with the provisions of that regulation, to the person who is seeking redress, or to his or her legal representative;

(i) contains details of the right to notify the concern, in relation to the actions or omissions of the Welsh NHS body, to the Public Services Ombudsman for Wales;

(j) offers the person who is seeking redress the opportunity to discuss the contents of the interim report with the responsible officer, designated in accordance with regulation 7, or a person acting on his or her behalf; and

(k) is signed by the responsible officer or a person acting on his or her behalf.

(2) Save where paragraph (3) applies, a Welsh NHS body must take all reasonable steps to send an interim report to the person who notified the concern within fifty working days beginning with the day on which it received notification of the concern.

(3) If a Welsh NHS body is not able to provide an interim report in accordance with paragraph (2), it must–

(a) notify the person who notified the concern accordingly and explain the reason why; and

(b) send the interim report as soon as reasonably practicable and within six months beginning

chwe mis sy'n cychwyn gyda'r diwrnod y cafodd yr hysbysiad o bryder.

(4) Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o chwe mis, rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder o'r rhesymau am yr oedi a pha bryd y gellir disgwyl cael yr adroddiad interim.

(5) Rhaid darparu adroddiad yr ymchwiliad, y cyfeirir ato yn rheoliad 46, i'r person a hysbysodd y pryder neu i'w gynrychiolydd cyfreithiol cyn gynted ag y bo'n rhesymol ymarferol, a hynny ddim hwyrach na deuddeng mis o'r dyddiad y cafodd y corff GIG Cymru yr hysbysiad o bryder.

(6) Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o ddeuddeng mis, rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder neu ei gynrychiolydd cyfreithiol o'r rhesymau am yr oedi a pha bryd y gellir disgwyl cael adroddiad yr ymchwiliad.

Ymateb i ymchwiliad o dan reoliad 39 pan fo corff GIG Cymru yn penderfynu nad oes atebolrwydd cymwys

41. Os yw corff GIG Cymru, yn dilyn ymchwiliad yn unol â rheoliad 39, yn penderfynu nad yw'r pryder a hysbyswyd yn unol â rheoliad 36, neu gan gorff GIG yr Alban neu gorff GIG Gogledd Iwerddon, yn cynnwys atebolrwydd cymwys, rhaid i'r corff GIG Cymru–

(a) hysbysu, mewn ysgrifen, y person a hysbysodd y pryder o'i benderfyniad, ac o'r rhesymau am ei benderfyniad;

(b) cynnig cyfarfod y person a hysbysodd y pryder, i drafod y penderfyniad;

(c) darparu manylion i'r person a hysbysodd y pryder, o'r hawl i hysbysu unrhyw bryder ynghylch gweithredoedd neu anweithiau'r corff GIG Cymru i Ombwdsmon Gwasanaethau Cyhoeddus Cymru; ac

(ch) anfon copi o'r llythyr penderfyniad ym mharagraff (a) at y corff GIG Lloegr, corff GIG yr Alban neu gorff GIG Gogledd Iwerddon.

Ffurf yr iawn

42.–(1) Mae iawn o dan y Rhan hon yn cynnwys–

(a) gwneud cynnig o ddigolllediad i fodloni unrhyw hawl i ddwyn achos sifil mewn perthynas ag atebolrwydd cymwys;

(b) rhoi esboniad;

(c) gwneud ymddiheuriad ysgrifenedig; ac

(ch) rhoi adroddiad ar y modd y gweithredwyd, neu y gweithredir yn y dyfodol, i rwystro achosion cyffelyb rhag digwydd eto.

(2) Caiff y digollediad y caniateir ei gynnig yn unol

with the day upon which it received notification of the concern.

(4) If exceptional circumstances mean that the six month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern of the reasons for the delay and when the interim report may be expected.

(5) The investigation report referred to in regulation 46 must be provided to the person who notified the concern, or his or her legal representative, as soon as reasonably practicable and not later than twelve months from the date that the Welsh NHS body received notification of the concern.

(6) If exceptional circumstances mean that the twelve month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern, or his or her legal representative, of the reasons for the delay and when the investigation report may be expected.

Response to an investigation under regulation 39 where a Welsh NHS body decides that there is no qualifying liability

41. Where following an investigation in accordance with regulation 39, a Welsh NHS body decides that the concern notified in accordance with regulation 36 or by a Scottish NHS body or Northern Irish NHS body does not involve a qualifying liability, the Welsh NHS body must–

(a) advise, in writing, the person who notified the concern of its decision and the reasons for its decision;

(b) offer to meet the person who notified the concern to discuss the decision;

(c) provide the person who notified the concern with details of the right to notify any concern about acts or omissions of the Welsh NHS body to the Public Services Ombudsman for Wales; and

(d) send a copy of the decision letter in paragraph (a) to the English NHS body, the Scottish NHS body or the Northern Irish NHS body.

Form of redress

42.–(1) Redress under this Part comprises–

(a) the making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of a qualifying liability;

(b) the giving of an explanation;

(c) the making of a written apology; and

(d) the giving of a report on the action which has been, or will be, taken to prevent similar cases arising.

(2) The compensation that may be offered in

â rheoliad 42(1)(a) fod ar ffurf ymuno mewn contract i ddarparu gofal neu driniaeth, neu ddigolledaid ariannol, neu'r ddau.

Argaeledd iawn

43.–(1) Nid oes iawn ar gael mewn perthynas ag atebolrwydd sydd, neu a fu, yn destun achos sifil.

(2) Os cychwynnir achos sifil o'r fath yn ystod ystyriaeth o iawn gan gorff GIG Cymru, rhaid terfynu'r ystyriaeth o iawn gan y corff GIG Cymru yn unol â'r Rhan hon, a rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder a'r corff GIG Lloegr, corff GIG yr Alban neu'r corff GIG Gogledd Iwerddon a hysbysodd y pryder wrth y corf GIG Cymru, yn unol â hynny.

Iawn – digolledaid ariannol

44.–(1) Caiff corff GIG Cymru wneud cynnig o iawn am atebolrwydd cymwys ar ffurf digolledaid ariannol o ddim mwy na £25,000.

(2) Pan fo corff GIG Cymru o'r farn bod y gwerth sydd i'w briodoli i'r atebolrwydd cymwys sy'n codi o ddarparu gwasanaethau cymwys yn fwy na'r terfyn a bennir ym mharagraff (1), rhaid peidio â chynnig iawn ar ffurf digolledaid ariannol yn unol â'r Rheoliadau hyn.

(3) Cyfrifir yr iawndal am boen, dioddefaint a cholled amwynder ar sail y gyfraith gyffredin. Caiff Gweinidogion Cymru, o bryd i'w gilydd, ddyroddi tariff digolledu.

(4) Os dyroddir tariff yn unol â pharagraff (3), mae cyrff GIG Cymru i'w ddefnyddio at ddibenion canllaw wrth ystyried swm y digolledaid ariannol sydd i'w gynnig yn unol â'r Rhan hon.

Atal dros dro gyfnod y cyfyngiad

45.–(1) Yn ystod y cyfnod pan fo atebolrwydd yn destun cais am iawn o dan y Rhan hon, atelir unrhyw gyfnod cyfyngiad ar gyfer dwyn achos sifil mewn perthynas â'r atebolrwydd hwnnw, a ragnodir gan neu o dan Ddeddf Cyfyngiadau 1980(**1**) neu unrhyw ddeddfiad arall, ac ni fydd amser yn treiglo at ddibenion cyfrifo unrhyw derfynau amser a ragnodir gan y deddfiadau hynny.

(2) At ddibenion y Rhan hon, ystyrir bod atebolrwydd yn destun cais am iawn–

(a) yn cychwyn o'r dyddiad y cafodd y corff GIG Lloegr, y corff GIG yr Alban neu'r corff GIG Gogledd Iwerddon yr hysbysiad gwreiddiol o

(**1**) 1980 p.58.

accordance with regulation 42(1)(a) can take the form of entry into a contract to provide care or treatment or of financial compensation, or both.

Availability of Redress

43.–(1) Redress is not available in relation to a liability that is or has been the subject of civil proceedings.

(2) If such civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress in accordance with this Part must cease and the Welsh NHS body must advise the person who notified the concern and the English NHS body, Scottish NHS body or Northern Irish NHS body that notified the concern to the Welsh NHS body accordingly.

Redress – financial compensation

44.–(1) A Welsh NHS body may make an offer of redress for a qualifying liability by way of financial compensation not exceeding £25,000.

(2) Where a Welsh NHS body considers that the value to be attributed to the qualifying liability arising from the provision of qualifying services exceeds the limit set out in paragraph (1), redress in the form of financial compensation must not be offered in accordance with these Regulations.

(3) The assessment of damages for pain, suffering and loss of amenity is calculated on the common law basis. Welsh Ministers may from time to time issue a compensation tariff.

(4) If a tariff is issued in accordance with paragraph (3), it is to be used for the purpose of guidance by Welsh NHS bodies when considering the amount of financial compensation to be offered in accordance with this Part.

Suspension of the limitation period

45.–(1) During the period in which a liability is the subject of an application for redress under this Part, any limitation period for the bringing of civil proceedings in respect of that liability which is prescribed by or under the Limitation Act 1980(**1**) or any other enactment is suspended and time will not run for the purposes of calculating any time limits prescribed by these enactments.

(2) For the purposes of this Part, a liability is to be considered as being the subject of an application for redress–

(a) beginning with the date on which the initial concern which became an application for redress was received by an English NHS body,

(**1**) 1980 c.58.

bryder, a ddaeth yn gais am iawn;

(b) yn ddarostyngedig i baragraffau (3), (4) a (5), hyd at a chan gynnwys yr amser y derbynnir cynnig o ddigolledaid ariannol yn unol â rheoliad 48 gan glaf neu ei gynrychiolydd drwy lofnodi cytundeb ffurfiol ac ildiad cyfreithiol yn unol â rheoliad 48(d), neu hyd nes gwrthodir cynnig o ddigolledaid o'r fath gan glaf neu ei gynrychiolydd.

(3) Nid ystyrir mwyach bod atebolrwydd yn destun cais am iawn ymhen naw mis calendr o'r dyddiad pan wneir cynnig o ddigolledaid ariannol gan y corff GIG Cymru mewn perthynas â'r atebolrwydd hwnnw.

(4) Mewn achosion pan fo cymeradwyaeth llys yn ofynnol ar gyfer unrhyw setliad a gynigir, megis yn yr amgylchiadau a amlinellir yn rheoliad 48(dd), os bydd cyfyngiad amser yn fater perthnasol, atelir cyfnod y cyfyngiad dros dro, hyd nes cyrhaeddir setliad a gymeradwyir gan y llys.

(5) Mewn achosion pan fo corff GIG Cymru yn dynodi, yn unol â rheoliad 48, ei fod wedi penderfynu nad oes atebolrwydd cymwys ac wedi penderfynu peidio â gwneud cynnig o iawn, nid ystyrir mwyach bod atebolrwydd yn destun cais am iawn ymhen naw mis calendr o'r dyddiad yr hysbysodd y corff GIG Cymru ei benderfyniad yn unol â rheoliad 48.

Adroddiad yr ymchwiliad

46.–(1) Rhaid i gorff GIG Cymru sicrhau bod canfyddiadau'r ymchwiliad i bryder, pan fo person yn ceisio iawn o dan y Rhan hon, yn cael eu cofnodi mewn adroddiad ar yr ymchwiliad.

(2) Rhaid i adroddiad ar ymchwiliad gynnwys y canlynol–

(a) copi o unrhyw dystiolaeth feddygol a gomisiynwyd yn unol â'r Rhan hon er mwyn canfod a oes atebolrwydd cymwys ai peidio, neu a gomisiynwyd i ganfod cyflwr a phrognosis;

(b) hysbysiad gan y corff GIG Cymru yn cadarnhau a oes, yn ei farn ef, atebolrwydd cymwys ai peidio; ac

(c) esboniad o'r farn a fynegir yn is-baragraff (b).

(3) Ac eithrio pan fo paragraff (4) yn gymwys, rhaid i'r corff GIG Cymru ddarparu copi o adroddiad yr ymchwiliad i'r person sy'n ceisio iawn o dan y Rhan hon neu i'w gynrychiolydd cyfreithiol, o fewn terfyn amser fel a bennir yn rheoliad 40(5) neu (6).

(4) Nid oes angen i'r corff GIG Cymru ddarparu copi

a Scottish NHS body or a Northern Irish NHS body;

(b) subject to paragraphs (3), (4) and (5), up to and including the time when an offer of financial compensation made in accordance with regulation 48 is accepted by a patient or his or her representative by signing a formal agreement and legal waiver in accordance with regulation 48(e) or until such time as an offer of such compensation is rejected by a patient or his or her representative.

(3) A liability will no longer be considered a subject of an application for redress nine calendar months from the date upon which the Welsh NHS body makes an offer of financial compensation in respect of that liability.

(4) In cases where court approval of a settlement proposed by an offer is required, such as in circumstances outlined in regulation 48(f), limitation, if limitation is an issue, is suspended until a settlement is reached which receives the approval of the court.

(5) In cases where a Welsh NHS body indicates, in accordance with regulation 48, that it has decided that there is no qualifying liability and has decided not to make an offer of redress, a liability will not be considered to be the subject of an application for redress nine calendar months from the date on which the Welsh NHS body communicated its decision in accordance with regulation 48.

Investigation report

46.–(1) A Welsh NHS body must ensure that the findings of the investigation of a concern in which a person is seeking redress under this Part are recorded in an investigation report.

(2) An investigation report will include the following–

(a) a copy of any medical evidence that has been commissioned in accordance with this Part in order to determine whether there is a qualifying liability or which has been commissioned to determine condition and prognosis;

(b) a statement by the Welsh NHS body confirming whether or not, in its opinion, there is a qualifying liability; and

(c) an explanation for the opinion expressed in sub-paragraph (b).

(3) Unless paragraph (4) applies, the Welsh NHS body must provide the person who is seeking redress under this Part, or his or her legal representative, with a copy of the investigation report within the time frame set out in regulation 40(5) or (6).

(4) No copy of the investigation report need be

o adroddiad yr ymchwiliad–

(a) cyn gwneud cynnig o iawn o dan y Rhan hon;

(b) cyn hysbysu ynghylch penderfyniad i beidio â gwneud cynnig o iawn;

(c) os terfynir, am unrhyw reswm, yr ymchwiliad i'r iawn yn unol â'r Rhan hon; neu

(ch) pan fo'r adroddiad yn cynnwys gwybodaeth sy'n debygol o beri niwed neu drallod sylweddol i'r claf neu i geisydd arall am iawn.

Cyngor cyfreithiol a chyfarwyddo arbenigwyr meddygol

47.–(1) Pan fo corff GIG Cymru wedi penderfynu bod atebolrwydd cymwys naill ai'n bodoli, neu y gall fodoli, yn unol â rheoliad 40 a'r Rhan hon, rhaid i'r corff GIG Cymru sicrhau–

(a) bod cyngor cyfreithiol ar gael i berson sy'n ceisio iawn o dan y Rhan hon, yn unol â darpariaethau canlynol y rheoliad hwn; a

(b) os oes angen cyfarwyddo arbenigwr neu arbenigwyr meddygol, y cyflawnir y cyfarwyddo ar y cyd gan y corff GIG Cymru a'r person a hysbysodd y pryder.

(2) Rhaid ceisio cyngor cyfreithiol gan y ffyrmiau cyfreithwyr hynny, yn unig, sydd ag arbenigedd cydnabyddedig ym maes esgeuluster clinigol. Cydnabyddir bod gan ffyrm yr arbenigedd angenrheidiol os oes ganddynt o leiaf un partner neu gyflogai sy'n aelod o Banel Esgeuluster Clinigol Cymdeithas y Cyfreithwyr(**1**) neu Weithredu yn erbyn Damweiniau Meddygol(**2**).

(3) Rhaid i gorff GIG Cymru sicrhau y bydd cyngor cyfreithiol di-dâl ar gael i'r person a hysbysodd y pryder mewn perthynas â'r materion canlynol–

(a) cyfarwyddo arbenigwyr meddygol ar y cyd, gan gynnwys ceisio eglurhad gan y cyfryw arbenigwyr ar faterion sy'n codi o'u hadroddiadau;

(b) unrhyw gynnig a wneir yn unol â'r Rhan hon;

(**1**) Mae Cymdeithas y Cyfreithwyr yn rhedeg cynllun achredu ar gyfer cyfreithwyr a Chymrodyr Sefydliad y Gweithredwyr Cyfreithiol (ILEX) sy'n arbenigo mewn achosion o esgeuluster clinigol. Mae gan gyfreithwyr a Chymrodyr ILEX hawl i gael eu rhestru fel aelodau o Banel Esgeuluster Clinigol Cymdeithas y Cyfreithwyr os ydynt yn gallu dangos, yn unol â gweithdrefn gyhoeddedig Cymdeithas y Cyfreithwyr, fod ganddynt ddigon o arbenigedd mewn materion esgeuluster clinigol.

(**2**) Elusen yw Gweithredu yn erbyn Damweiniau Meddygol (AVMA) a sefydlwyd i hybu diogelwch cleifion. Mae'n rhedeg cynllun achredu ar gyfer cyfreithwyr a Chymrodyr Sefydliad y Gweithredwyr Cyfreithiol (ILEX). Gall cyfreithwyr a Chymrodyr ILEX sy'n gallu dangos eu bod yn bodloni meini prawf cyhoeddedig ar gyfer dangos arbenigedd ym maes esgeuluster clinigol ddod yn aelodau o Banel Esgeuluster Clinigol AVMA.

provided by the Welsh NHS body–

(a) before an offer of redress under this Part is made;

(b) before a decision not to make an offer of redress is communicated;

(c) if the investigation of redress in accordance with this Part is for any reason terminated; or

(d) where the report contains information likely to cause the patient or other applicant for redress significant harm or distress.

Legal advice and instruction of medical experts

47.–(1) Where a Welsh NHS body has determined that a qualifying liability exists, or may exist, in accordance with regulation 40 and this Part, the Welsh NHS body must ensure–

(a) that legal advice is available to a person seeking redress under this Part in accordance with the following provisions of this regulation; and

(b) if a medical expert or experts need to be instructed that such instruction is carried out jointly by the Welsh NHS body and the person who notified the concern.

(2) Legal advice must only be sought from firms of solicitors who have a recognised expertise in the field of clinical negligence. Firms will be recognised as having the necessary expertise if they have at least one partner or employee who is a member of the Law Society Clinical Negligence Panel (**1**) or the Action Against Medical Accidents Clinical Negligence Panel (**2**).

(3) A Welsh NHS body must ensure that legal advice without charge is available to the person who notified the concern in relation to the following matters–

(a) the joint instruction of medical experts, including the seeking of clarification from such experts of issues arising from their reports;

(b) any offer that is made in accordance with this Part;

(**1**) The Law Society runs an accreditation scheme for solicitors and Fellows of the Institute of Legal Executives (FILEX) who specialise in clinical negligence cases. Solicitors and FILEX who are able to demonstrate, in accordance with the Law Society's published procedure, that they are sufficiently expert in clinical negligence matters are eligible to be listed as a member of the Law Society Clinical Negligence Panel.

(**2**) Action Against Medical Accidents (AVMA) is a charity established to promote patient safety. It runs an accreditation scheme for solicitors and Fellows of the Institute of Legal Executives (FILEX). Solicitors and FILEX who can demonstrate that they meet AVMA's published criteria for demonstrating expertise in the field of clinical negligence can become members of AVMA's Clinical Negligence Panel.

(c) unrhyw wrthodiad i wneud cynnig o'r fath; ac

(ch) unrhyw gytundeb setlo a gynigir.

(4) Yn ddarostyngedig i unrhyw hawliau sydd gan gorff GIG Cymru i adennill gwariant o'r fath oddi ar gorff GIG Lloegr, rhaid i gost y cyfryw gyngor cyfreithiol a chostau sy'n codi o gyfarwyddo'r cyfryw arbenigwyr meddygol gael eu dwyn yn gyfan gwbl gan y corff GIG Cymru.

Iawn – hysbysu ynghylch penderfyniad

48. Pan fo corff GIG Cymru yn penderfynu gwneud cynnig o iawn ar ffurf digolledìad ariannol neu ymuno mewn contract i ddarparu gofal neu driniaeth, neu'r ddau, neu'n penderfynu peidio â gwneud cynnig o iawn, ar y sail nad oes atebolrwydd cymwys, rhaid iddo–

(a) anfon y cynnig neu'r hysbysiad o'r penderfyniad i beidio â gwneud cynnig at y person a hysbysodd y pryder o fewn deuddeng mis o'r dyddiad y hysbyswyd y pryder i'r corff GIG Cymru. Os yw amgylchiadau eithriadol yn peri na ellir cadw at y cyfnod o ddeuddeng mis, rhaid i'r corff GIG Cymru hysbysu'r person a hysbysodd y pryder neu ei gynrychiolydd cyfreithiol o'r rhesymau am yr oedi a pha bryd y gwneir penderfyniad ynglŷn â'r cais am iawn;

(b) hysbysu'r person hwnnw neu ei gynrychiolydd cyfreithiol bod rhaid iddo ymateb i'r cynnig o setliad neu'r penderfyniad i beidio â gwneud cynnig o setliad o fewn chwe mis o'r dyddiad y gwneir y cynnig neu'r penderfyniad;

(c) yn ddarostyngedig i baragraff (ch), rhaid i'r corff GIG Cymru roi gwybod hefyd, os na fydd yn bosibl ymateb i'r cynnig o setliad neu'r penderfyniad i beidio â gwneud cynnig o setliad o fewn chwe mis, oherwydd amgylchiadau eithriadol, y bydd rhaid hysbysu'r corff GIG Cymru o'r rhesymau am yr oedi, a pha bryd y cyflwynir ymateb;

(ch) rhoi gwybod i berson neu ei gynrychiolydd cyfreithiol, os gofynnir am estyn yr amser a ganiateir i ymateb i gynnig o setliad neu benderfyniad i beidio â gwneud cynnig o setliad, y bydd yn ofynnol ymateb o fewn naw mis calendr o ddyddiad y cynnig, gan mai'r dyddiad hwnnw, yn unol â rheoliad 45(3) a (5) yw dyddiad cychwyn cyfnod y cyfyngiad;

(d) rhoi gwybod, os gwneir cynnig, y bydd y setliad a gynigir ar ffurf cytundeb ffurfiol, ac y bydd rhaid i'r cytundeb gynnwys ildiad o unrhyw hawl i ddwyn achos sifil mewn perthynas â'r atebolrwydd cymwys y mae'r setliad yn ymwneud ag ef;

(dd) rhoi gwybod, o dan amgylchiadau priodol, y byddai'r cytundeb setlo a gynigir yn

(c) any refusal to make such an offer; and

(d) any settlement agreement that is proposed.

(4) Subject to any rights that a Welsh NHS body has to recover such expenditure from an English NHS body,, the cost of such legal advice and costs arising from the instruction of such medical experts must be borne in their entirety by the Welsh NHS body.

Redress – communication of a decision

48. Where a Welsh NHS body decides to make an offer of redress by way of financial compensation or entry into a contract to provide care or treatment or both or determines that it will not make an offer of redress on the basis that there is no qualifying liability, it must–

(a) send the offer or the notification of the decision not to make an offer to the person who notified the concern within twelve months of the date on which the concern was notified to the Welsh NHS body. If exceptional circumstances mean that the twelve month period cannot be adhered to, the Welsh NHS body must advise the person who notified the concern, or his or her legal representative, of the reasons for the delay and when a decision in respect of the application for redress will be made;

(b) advise that person or his or her legal representative that he or she must respond to the offer of settlement or a decision not to make an offer of settlement within six months of the date that it is made;

(c) subject to paragraph (d), advise that if, as a result of exceptional circumstances, it will not be possible to respond to the offer of settlement or the decision not to make an offer of settlement within six months, the Welsh NHS body must be advised of the reasons for the delay in responding and when a response will be submitted;

(d) advise a person or his or her legal representative that if an extension of time is sought to respond to an offer of settlement or a decision not to make an offer of settlement, a response is required within nine calendar months of the date of the offer as that is the time when, in accordance with regulation 45(3) and (5), limitation starts to run;

(e) advise, if an offer is made, that the settlement proposed by the offer will be by way of a formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates;

(f) advise that, in appropriate circumstances, the settlement agreement proposed will be subject

ddarostyngedig i'w gymeradwyo gan lys, megis mewn achosion pan fo'r person y mae'r atebolrwydd cymwys yn ymwneud ag ef–

(i) yn blentyn; neu

(ii) heb alluedd yn yr ystyr a roddir i "capacity" yn Neddf Galluedd Meddyliol 2005(**1**); ac

(e) rhoi gwybod, os yw'n ofynnol cael cymeradwyaeth llys ar gyfer setliad, y byddai rhaid i'r corff GIG Cymru dalu'r costau cyfreithiol rhesymol a fyddai'n gysylltiedig â chael y cyfryw gymeradwyaeth.

RHAN 8

DYSGU O'R PRYDERON

Dysgu o'r pryderon

49.–(1) Rhaid i bob corff cyfrifol sicrhau bod trefniadau wedi eu sefydlu ganddo i adolygu canlyniad unrhyw bryder a fu'n destun ymchwiliad o dan y Rheoliadau hyn, er mwyn sicrhau y rhoddir sylw i unrhyw ddiffygion a ganfuwyd yn ystod yr ymchwiliad yn y modd y gweithredodd y corff cyfrifol neu ei ddarpariaeth o wasanaethau, drwy–

(a) gweithredu ynglŷn â'r diffygion; a

(b) monitro'r diffygion,

er mwyn sicrhau bod unrhyw wersi a ddysgwyd yn cael eu nodi a'u lledaenu ledled y corff hwnnw, i wella'r gwasanaethau a ddarperir ganddo ac atal diffygion o'r fath rhag digwydd eto.

(2) Cyfrifoldeb y person a ddynodir yn unol â rheoliad 6 yw gweithredu'r trefniadau sy'n ofynnol gan y Rhan hon.

RHAN 9

MONITRO'R BROSES

Monitro gweithrediad y trefniadau i ymdrin â phryderon

50. At y diben o fonitro gweithrediad y trefniadau i ymdrin â phryderon o dan y Rheoliadau hyn, rhaid i bob corff cyfrifol gadw cofnod o'r materion canlynol–

(a) pob pryder a hysbysir iddo gan gynnwys, yn achos cyrff GIG Cymru, unrhyw bryderon a hysbysir yn unol â darpariaethau Rhan 7;

(b) canlyniad pob pryder; ac

(**1**) 2005 p.9.

to approval by a court in cases such as those where the person to whom the qualifying liability relates–

(i) is a child; or

(ii) lacks capacity within the meaning of the Mental Capacity Act 2005(**1**); and

(g) advise that where court approval of a settlement is required, that the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

PART 8

LEARNING FROM CONCERNS

Learning from concerns

49.–(1) Each responsible body must ensure that it has in place arrangements to review the outcome of any concern that has been subject to an investigation under these Regulations in order to ensure that any deficiencies in its actions or its provision of services which are identified during the investigation are–

(a) acted upon; and

(b) monitored,

in order to ensure that any lessons learned are identified and promulgated throughout that body in order to improve the services that it provides and to seek to avoid such deficiencies recurring.

(2) The operation of the arrangements required by this Part is the responsibility of the person designated in accordance with regulation 6.

PART 9

MONITORING THE PROCESS

Monitoring the operation of arrangements for dealing with concerns

50. For the purposes of monitoring the operation of the arrangements for dealing with concerns under these Regulations each responsible body must maintain a record of the following matters–

(a) each concern notified to it, including in the case of Welsh NHS bodies, any concerns notified in accordance with the provisions of Part 7;

(b) the outcome of each concern; and

(**1**) 2005 c.9.

(c) os hysbyswyd y person a hysbysodd y pryder gan y corff cyfrifol o'r canlynol–

(i) y cyfnod tebygol o amser a gymerid i ddyroddi ymateb yn unol â rheoliad 22(4)(c); neu

(ii) unrhyw estyniad i'r cyfnod hwnnw,

pa un a anfonwyd ymateb ai peidio at y person a hysbysodd y pryder, gan roi manylion am ganlyniad yr ymchwiliad i'r pryder, o fewn y cyfnod hwnnw neu unrhyw gyfnod estynedig.

Yr adroddiad blynyddol

51.–(1) Rhaid i bob corff cyfrifol baratoi adroddiad blynyddol ar gyfer pob blwyddyn, a rhaid i'r adroddiad hwnnw–

(a) nodi nifer y pryderon a hysbyswyd wrth y corff cyfrifol gan gynnwys, yn achos cyrff GIG Cymru, unrhyw bryderon a hysbyswyd wrtho yn unol â darpariaethau Rhan 7;

(b) nodi nifer y pryderon y penderfynodd y corff cyfrifol oedd â sail dda iddynt;

(c) nodi nifer y pryderon yr hysbyswyd y corff cyfrifol eu bod wedi eu hysbysu i Ombwdsmon Gwasanaethau Cyhoeddus Cymru;

(ch) rhoi crynodeb o'r canlynol–

(i) y materion a oedd yn destun y pryderon a hysbyswyd wrth y corff cyfrifol;

(ii) unrhyw faterion o bwysigrwydd cyffredinol a oedd yn codi o'r pryderon hynny neu'r modd y'u triniwyd;

(iii) unrhyw faterion y gweithredwyd, neu y bwriedir gweithredu ynglŷn â hwy er mwyn gwella'r gwasanaethau, o ganlyniad i'r pryderon hynny.

(2) Mae'r paragraff hwn yn gymwys i gorff cyfrifol sydd–

(a) yn gorff GIG Cymru ac eithrio Bwrdd Iechyd Lleol; neu

(b) yn ddarparwr gofal sylfaenol neu ddarparwr annibynnol,

ac y sydd, mewn unrhyw flwyddyn, yn darparu neu'n cytuno i ddarparu gwasanaethau o dan drefniadau gyda Bwrdd Iechyd Lleol.

(3) Rhaid i gorff cyfrifol y mae paragraff (2) yn gymwys iddo anfon copi o'i adroddiad blynyddol at y Bwrdd Iechyd Lleol a drefnodd ar gyfer darparu'r gwasanaethau gan y corff cyfrifol.

(c) where the responsible body informed the person who notified the concern of–

(i) the likely period within which a response would be issued in accordance with regulation 22(4)(c); or

(ii) any extension to that period,

whether a response detailing the outcome of the investigation of the concern was sent to the person who notified the concern within that period, or any extended period.

Annual report

51.–(1) Each responsible body must prepare an annual report for each year which must–

(a) specify the number of concerns which were notified to the responsible body, including, in the case of Welsh NHS bodies, any concerns that were notified to it in accordance with the provisions of Part 7;

(b) specify the number of concerns which the responsible body determined to be well-founded;

(c) specify the number of concerns that the responsible body has been advised have been notified to the Public Services Ombudsman for Wales;

(d) summarise–

(i) the subject matter of concerns which were notified to the responsible body;

(ii) any matters of general importance arising out of those concerns, or the way in which they were handled;

(iii) any matters where action has been taken or is to be taken to improve services as a consequence of those concerns.

(2) This paragraph applies to a responsible body which is–

(a) a Welsh NHS body other than a Local Health Board; or

(b) a primary care provider or an independent provider,

and which in any year provides, or agrees to provide, services under arrangements with a Local Health Board.

(3) A responsible body to which paragraph (2) applies must send a copy of its annual report to the Local Health Board which arranged for the provision of the services by the responsible body.

RHAN 10

DARPARIAETHAU TROSIANNOL A CHANLYNIADOL A DIRYMIADAU

Darpariaethau trosiannol

52.–(1) Yn y rheoliad hwn, ystyr "y darpariaethau cwynion blaenorol" ("*the former complaints provisions*") yw unrhyw rai o'r cyfarwyddiadau mewn perthynas â chwynion a ddirymir gan reoliad 53.

(2) Cyn 1 Ebrill 2011–

(a) os gwnaed cwyn yn unol ag unrhyw un o'r darpariaethau cwynion blaenorol; a

(b) os nad yw'r gŵyn wedi ei heithrio o'i hystyried gan unrhyw ddarpariaeth o fewn y darpariaethau cwynion blaenorol,

gellir ymchwilio iddi, neu barhau i ymchwilio iddi, fel y bo'n briodol, yn unol â'r darpariaethau hynny.

(3) Yn unol ag unrhyw un o'r darpariaethau cwynion blaenorol–

(a) os cynhaliwyd a chwblhawyd ymchwiliad i gŵyn gan reolwr cwynion neu hwylusydd cwynion annibynnol; a

(b) os gwnaed cais gan y person a wnaeth y gŵyn honno am adolygiad gan banel adolygu annibynnol,

rhaid trin y cais yn ynol â'r darpariaethau cwynion blaenorol.

(4) Ac eithrio mewn perthynas â chwyn a fyddai'n ddarostyngedig i'r trefniadau yn Rhan 7 o'r Rheoliadau hyn, yn achos cwyn, y digwyddodd y mater sy'n destun iddi cyn 1 Ebrill 2011–

(a) os na wnaed y gŵyn yn unol ag unrhyw un o'r darpariaethau cwynion blaenorol; a

(b) os nad yw wedi ei gwahardd rhag ei hystyried gan unrhyw ddarpariaeth o fewn y Rheoliadau hyn,

caniateir hysbysu, ystyried ac ymchwilio i'r gŵyn yn unol â'r Rheoliadau hyn.

(5) Ni fydd cwynion ynghylch gwasanaethau a ddarparwyd gan gyrff GIG Lloegr, cyrff GIG yr Alban neu gyrff GIG Gogledd Iwerddon, fel y'u diffinnir yn rheoliad 34, a wnaed cyn 1 Hydref 2011 yn cael eu hystyried o dan Ran 7 o'r Rheoliadau hyn.

Dirymiadau

53. Yn ddarostyngedig i reoliad 52, dirymir y cyfarwyddiadau canlynol, a wnaed o dan y darpariaethau a restrir yn rheoliad 52(1)(a):

(a) y Cyfarwyddiadau i Ymddiriedolaethau GIG a

PART 10

TRANSITIONAL AND CONSEQUENTIAL PROVISIONS AND REVOCATIONS

Transitional provisions

52.–(1) In this regulation "the former complaints provisions" means any of the directions in relation to complaints which are revoked by regulation 53.

(2) Where before 1 April 2011–

(a) a complaint has been made in accordance with any of the former complaints provisions; and

(b) it is not excluded from consideration by any provision within the former complaints provisions,

it may be investigated, or continue to be investigated, as appropriate, in accordance with those provisions.

(3)Where in accordance with any of the former complaints provisions–

(a) an investigation of a complaint has been conducted and completed by a complaints manager or an independent complaints facilitator; and

(b) the person who made the complaint has made a request for a review by an independent review panel,

the request must be dealt with in accordance with the former complaints provisions.

(4) Save in respect of a complaint which would be subject to the arrangements in Part 7 of these Regulations, where a complaint, the subject matter of which occurred before 1 April 2011–

(a) has not been made in accordance with any of the former complaints provisions; and

(b) it is not excluded from consideration by any provision within these Regulations,

it may be notified, considered and investigated in accordance with these Regulations.

(5) Complaints about services provided by English NHS bodies, Scottish NHS bodies or Northern Irish NHS bodies, as defined in regulation 34, made before 1 October 2011 will not be considered under Part 7 of these Regulations.

Revocations

53. Subject to regulation 52, the following directions made under the provisions listed in regulation 52(1)(a) are revoked:

(a) the Directions to NHS Trust and Local Health

Byrddau Iechyd Lleol ar Weithdrefnau Cwynion Ysbytai, a wnaed ar 27 Mawrth 2003;

(b) y Cyfarwyddiadau i Fyrddau Iechyd Lleol ar Ymdrin â Chwynion ynghylch Ymarferwyr Gwasanaethau Iechyd Teuluol, Darparwyr Gwasanaethau Meddygol Personol a Darparwyr Gwasanaethau Deintyddol Personol ac eithrio'r Gwasanaethau Deintyddol Personol a Ddarperir gan Ymddiriedolaethau GIG, a wnaed ar 27 Mawrth 2003; ac

(c) Cyfarwyddiadau Amrywiol i Fyrddau Iechyd Lleol ar Ymdrin â Chwynion, a wnaed ar 27 Mawrth 2003.

Darpariaethau canlyniadol a throsiannol

54. Mae Atodlen 2 (Darpariaethau Canlyniadol a Throsiannol) yn cael effaith.

Boards on Hospital Complaints Procedures, made on 27 March 2003;

(b) the Directions to Local Health Boards on Dealing with Complaints about Family Health Services Practitioners, Providers of Personal Medical Services and Providers of Personal Dental Services, other than Personal Dental Services Provided by NHS Trusts, made on 27 March 2003; and

(c) Miscellaneous Directions to Local Health Boards for Dealing with Complaints, made on 27 March 2003.

Consequential and transitional provisions

54. Schedule 2 (Consequential and Transitional Provisions) has effect.

Edwina Hart

Y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru

8 Mawrth 2011

Minister for Health and Social Services, one of the Welsh Ministers

8 March 2011

ATODLEN 1

Rhaglith

DARPARIAETHAU SY'N RHOI'R PWERAU A ARFERWYD WRTH WNEUD Y RHEOLIADAU HYN

(1)	(2)
Darpariaeth	*Diwygiadau perthnasol*
Deddf Iechyd a Gofal Cymdeithasol (Iechyd Cymunedol a Safonau) 2003(1)	
Adran 113(2)	Mewnosodwyd paragraff (d) gan Fesur Gwneud Iawn am Gamweddau'r GIG (Cymru) 2008, adran 10.
Adran 113(3)	Diddymwyd paragraff (b) gan Ddeddf Iechyd a Gofal Cymdeithasol 2008, adran 95 a pharagraff 45 o Atodlen 5 ac adran 166 ac Atodlen 15(**2**).
Adran 113(4)(aa) a (b)	Mewnosodwyd paragraff (aa) gan Ddeddf Ombwdsmon Gwasanaethau Cyhoeddus (Cymru) 2005, adran 39(1) a pharagraffau 74 a 75 o Atodlen 6(**3**).
Adran 115(1)	
Adran 115(2)	
Adran 115(4)	
Adran 115(5)	
Adran 115(6)	
Adran 195	
Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(4)	
Adran 187	
Adran 206	

SCHEDULE 1

Preamble

PROVISIONS CONFERRING POWERS EXERCISED IN MAKING THESE REGULATIONS

(1)	(2)
Provision	*Relevant amendments*
Health and Social Care (Community Health and Standards) Act 2003(1)	
Section 113(2)	Paragraph (d) was inserted by the NHS Redress (Wales) Measure 2008, section 10.
Section 113(3)	Paragraph (b) was repealed by the Health and Social Care Act 2008, section 95 and paragraph 45 of Schedule 5 and section 166 and Schedule 15(**2**).
Section 113(4)(aa) and (b)	Paragraph (aa) was inserted by the Public Services Ombudsman (Wales) Act 2005, section 39(1) and paragraphs 74 and 75 of Schedule 6(**3**).
Section 115(1)	
Section 115(2)	
Section 115(4)	
Section 115(5)	
Section 115(6)	
Section 195	
National Health Service (Wales) Act 2006(4)	
Section 187	
Section 206	

Mesur Gwneud Iawn am Gamweddau'r GIG (Cymru) 2008(5)	
Adran 1	
Adran 2	
Adran 3	
Adran 4	
Adran 5	
Adran 6	
Adran 7	
Adran 9	
Adran 11	
Adran 12	
(1) 2003 p.43. (2) 2008 p.14. (3) 2005 p.10. (4) 2006 p.42. (5) 2008 mccc 1.	

NHS Redress (Wales) Measure 2008(5)	
Section 1	
Section 2	
Section 3	
Section 4	
Section 5	
Section 6	
Section 7	
Section 9	
Section 11	
Section 12	
(1) 2003 c.43. (2) 2008 c.14. (3) 2005 c.10. (4) 2006 c.42. (5) 2008 nawm 1.	

ATODLEN 2

Rheoliad 54

DARPARIAETHAU CANLYNIADOL A THROSIANNOL

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Offthalmig Cyffredinol) 1986

1.–(1) Diwygir Atodlen 1 (Telerau Gwasanaethu) i Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Offthalmig Cyffredinol) 1986(**1**) fel a ganlyn.

(2) O flaen paragraff 8A (Cwynion) mewnosoder–

"**Complaints and Concerns**

8ZA

(1) A contractor must have in place–

(a) arrangements for the handling and consideration of complaints about any matter connected with the provision of general ophthalmic services which comply with the provisions of paragraph 8A for the handling and consideration of any complaints–

(i) which were made prior to 1 April 2011; and

(ii) in respect of which the complaints process has not yet been completed, and

(b) arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns notified on or after 1 April 2011. References in paragraphs 8B and 8C to a concern are to a concern notified in accordance with those Regulations.".

(3) Yn lle'r pennawd mewn perthynas â pharagraff 8A (Cwynion), rhodder–

"**Complaints received prior to 1 April 2011**";

(4) Yn lle paragraff 8B rhodder y canlynol–

"**Co-operation with investigations**

8B

(1) A contractor must co-operate with any investigation of a complaint or a concern in relation to any matter reasonably connected to the contractor's provision of general ophthalmic services undertaken by a "relevant body", which includes–

(a) the Local Health Board;

(**1**) O.S. 1986/975.

SCHEDULE 2

Regulation 54

CONSEQUENTIAL AND TRANSITIONAL PROVISIONS

Amendment of the National Health Service (General Ophthalmic Services) Regulations 1986

1.–(1) Schedule 1 (Terms of Service) to the National Health Service (General Ophthalmic Services) Regulations 1986(**1**) is amended as follows.

(2) Before paragraph 8A (Complaints) insert–

"**Complaints and Concerns**

8ZA

(1) A contractor must have in place–

(a) arrangements for the handling and consideration of complaints about any matter connected with the provision of general ophthalmic services which comply with the provisions of paragraph 8A for the handling and consideration of any complaints–

(i) which were made prior to 1 April 2011; and

(ii) in respect of which the complaints process has not yet been completed, and

(b) arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns notified on or after 1 April 2011. References in paragraphs 8B and 8C to a concern are to a concern notified in accordance with those Regulations.".

(3) For the heading relating to paragraph 8A (Complaints) substitute –

"**Complaints received prior to 1 April 2011**";

(4) For paragraph 8B substitute the following–

"**Co-operation with investigations**

8B

(1) A contractor must co-operate with any investigation of a complaint or a concern in relation to any matter reasonably connected to the contractor's provision of general ophthalmic services undertaken by a "relevant body", which includes–

(a) the Local Health Board;

(**1**) S.I. 1986/975.

(b) the Welsh Ministers; or

(c) the Public Services Ombudsman for Wales.

(2) The co-operation required by sub-paragraph (1) includes–

(a) answering questions reasonably put to the contractor by a relevant body;

(b) providing any information relating to the complaint or concern reasonably required by a relevant body; and

(c) attending any meeting to consider the complaint or the concern (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given), if the contractor's presence is reasonably required by a relevant body.".

(5) Yn lle'r pennawd i baragraff 8C a pharagraffau 8C(1) a (2), rhodder y canlynol–

"Complaints made against and concerns notified about ophthalmic medical practitioners

8C

(1) Where a contractor who, being an ophthalmic medical practitioner, also performs primary medical services under a GMS contract for any person for whom he provides general ophthalmic services, the complaints procedure or procedure for notifying concerns established and operated in accordance with the terms of that GMS contract shall apply in relation to any matter reasonably connected with his provision of general ophthalmic services as it applies as respects the provision of services under the GMS contract.

(2) Accordingly, any requirement as to co-operation with investigations of complaints or concerns by other bodies imposed on a GMS contractor under the term of his contract which gives effect to paragraph 95 of Schedule 2 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 also applies in relation to complaints or concerns about such matters.".

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992

2.–(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(**1**) fel a ganlyn.

(2) Yn Rhan 4 o Atodlen 2 (Llywodraethu Clinigol a Chwynion), yn lle paragraff 28 (Cwynion) rhodder–

"Complaints and Concerns

28.

(1) A chemist must have in place–

(**1**) O.S. 1992/662.

(b) the Welsh Ministers; or

(c) the Public Services Ombudsman for Wales.

(2) The co-operation required by sub-paragraph (1) includes–

(a) answering questions reasonably put to the contractor by a relevant body;

(b) providing any information relating to the complaint or concern reasonably required by a relevant body; and

(c) attending any meeting to consider the complaint or the concern (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given), if the contractor's presence is reasonably required by a relevant body.".

(5) For the heading to paragraph 8C and paragraphs 8C(1) and (2), substitute the following–

"Complaints made against and concerns notified about ophthalmic medical practitioners

8C

(1) Where a contractor who, being an ophthalmic medical practitioner, also performs primary medical services under a GMS contract for any person for whom he provides general ophthalmic services, the complaints procedure or procedure for notifying concerns established and operated in accordance with the terms of that GMS contract shall apply in relation to any matter reasonably connected with his provision of general ophthalmic services as it applies as respects the provision of services under the GMS contract.

(2) Accordingly, any requirement as to co-operation with investigations of complaints or concerns by other bodies imposed on a GMS contractor under the term of his contract which gives effect to paragraph 95 of Schedule 2 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 also applies in relation to complaints or concerns about such matters.".

Amendment of the National Health Service (Pharmaceutical Services) Regulations 1992

2.–(1) The National Health Service (Pharmaceutical Services) Regulations 1992(**1**) are amended as follows.

(2) In Part 4 of Schedule 2 (Clinical Governance and Complaints), for paragraph 28 (Complaints) substitute–

"Complaints and Concerns

28.

(1) A chemist must have in place–

(**1**) S.I. 1992/662.

(a) arrangements for the handling and consideration of complaints about any matter connected with the provision of pharmaceutical services which comply with the provisions of paragraph 10A and 10B of Schedule 2 to these Regulations as they apply on 31 March 2005 for the handling and consideration of any complaints–

(i) which were made prior to 1 April 2011; and

(ii) in respect of which the complaints process has not yet been completed, and

(b) arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns notified on or after 1 April 2011.".

(3) Yn Rhan 6 o Atodlen 2 (Telerau Gwasanaethu ar gyfer Meddygon sy'n darparu Gwasanaethau Fferyllol)–

(a) yn lle'r pennawd i baragraff 41 (Gweithdrefnau cwynion) rhodder–

"**Complaints and concerns**";

(b) ym mharagraff 41(1)(a) yn lle "paragraph 90" rhodder "paragraphs 89A and 90";

(c) ym mharagraff 41(2) ar ôl "complaints" mewnosoder "or concerns notified".

(4) Yn Atodlen 2A (Telerau Gwasanaethu Cyflenwyr Offer)–

(a) ar ôl paragraff 21 (Bwrdd Iechyd Lleol Cartref cyrff corfforaethol) mewnosoder paragraff 21A newydd–

"**Concerns notified on or after 1 April 2011**

21A

A supplier of appliances must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011.";

(b) yn lle'r pennawd ar gyfer paragraff 22 (Cwynion), rhodder–

"**Complaints made prior to 1 April 2011**";

(c) yn lle paragraff 22(1) rhodder–

"A supplier of appliances must establish and operate in accordance with this paragraph a procedure (in this paragraph referred to as a "complaints procedure") to deal with any complaints made prior to 1 April 2011 by or on behalf of any person to whom the supplier of appliances has provided pharmaceutical services.".

(a) arrangements for the handling and consideration of complaints about any matter connected with the provision of pharmaceutical services which comply with the provisions of paragraph 10A and 10B of Schedule 2 to these Regulations as they apply on 31 March 2005 for the handling and consideration of any complaints–

(i) which were made prior to 1 April 2011; and

(ii) in respect of which the complaints process has not yet been completed, and

(b) arrangements which comply with the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, for the handling and consideration of any concerns notified on or after 1 April 2011.".

(3) In Part 6 of Schedule 2 (Terms of Service for Doctors who provide Pharmaceutical Services)–

(a) for the heading relating to paragraph 41 (Complaints procedures) substitute–

"**Complaints and concerns**";

(b) in paragraph 41(1)(a) for "paragraph 90" substitute "paragraphs 89A and 90";

(c) in paragraph 41(2) after "complaints" insert "or concerns notified".

(4) In Schedule 2A (Terms of Service of Suppliers of Appliances)–

(a) after paragraph 21 (Home Local Health Board of bodies corporate) insert a new paragraph 21A–

"**Concerns notified on or after 1 April 2011**

21A

A supplier of appliances must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011.";

(b) for the heading to paragraph 22 (Complaints), substitute–

"**Complaints made prior to 1 April 2011**";

(c) for paragraph 22(1) substitute–

"A supplier of appliances must establish and operate in accordance with this paragraph a procedure (in this paragraph referred to as a "complaints procedure") to deal with any complaints made prior to 1 April 2011 by or on behalf of any person to whom the supplier of appliances has provided pharmaceutical services.".

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004

3.–(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Meddygol Cyffredinol) (Cymru) 2004(**1**) fel a ganlyn.

(2) Yn Atodlen 6 (telerau contractiol eraill), o flaen Rhan 6 (Cwynion) mewnosoder–

"**Part 5A**

Concerns notified on or after 1 April 2011

89A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.".

(3) Yn Rhan 6 o Atodlen 6–

(a) yn lle'r pennawd i baragraff 90 (Gweithdrefn gwynion), rhodder–

"**Complaints received prior to 1 April 2011**";

(b) ym mharagraff 90, yn lle is-baragraff (1), rhodder y canlynol–

"(1) In respect of any complaints made prior to 1 April 2011in relation to any matter reasonably connected with the provision of services under the contract which have not been resolved by that date, the contractor must continue to deal with such complaints in accordance with the requirements of paragraphs 91 to 94 and 96.";

(c) ym mharagraff 95 (cydweithredu ag ymchwiliadau)–

(i) ar ôl "complaint", ym mhob lle y mae'n digwydd, mewnosoder "or a concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011";

(ii) yn lle is-baragraff (1)(a)(iii) rhodder–

"(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; and".

(4) Ym mharagraff 98 o Ran 7 o Atodlen 6 (Datrys anghydfodau: contractau ac eithrio contractau GIG), yn lle'r geiriau "complaints procedure pursuant to Part 6" rhodder "procedures for notifying concerns or making complaints pursuant to Parts 5A and 6".

(5) Yn Atodlen 10 (gwybodaeth sydd i'w chynnwys mewn taflenni gwybodaeth practis), yn lle paragraff 24, rhodder–

(**1**) O.S. 2004/478 (Cy.48).

Amendment of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004

3.–(1) The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**1**) are amended as follows.

(2) In Schedule 6 (other contractual terms), before Part 6 (Complaints) insert–

"**Part 5A**

Concerns notified on or after 1 April 2011

89A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.".

(3) In Part 6 of Schedule 6–

(a) for the heading relating to paragraph 90 (Complaints procedure), substitute–

"**Complaints received prior to 1April 2011**";

(b) in paragraph 90, for sub-paragraph (1), substitute the following–

"(1) In respect of any complaints made prior to 1 April 2011 in relation to any matter reasonably connected with the provision of services under the contract which have not been resolved by that date, the contractor must continue to deal with such complaints in accordance with the requirements of paragraphs 91 to 94 and 96.";

(c) in paragraph 95 (co-operation with investigations)–

(i) after "complaint" in each place it occurs insert "or a concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ";

(ii) for sub-paragraph (1)(a)(iii) substitute–

"(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; and".

(4) In paragraph 98 of Part 7 of Schedule 6 (Dispute resolution: non-NHS contracts), for "complaints procedure pursuant to Part 6" substitute "procedures for notifying concerns or making complaints pursuant to Parts 5A and 6".

(5) In Schedule 10 (information to be included in practice information leaflets), for paragraph 24 substitute–

(**1**) S.I. 2004/478 (W.48).

"**24**

How patients may–

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 6;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of service.".

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Deintyddol Cyffredinol) (Cymru) 2006

4.–(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Contractau Gwasanaethau Deintyddol Cyffredinol) (Cymru) 2006(**1**) fel a ganlyn.

(2) Yn Atodlen 3 (telerau contractiol eraill)–

(a) yn Rhan 5 (Cofnodion, Gwybodaeth, Hysbysiadau a Hawliau Mynediad), yn lle paragraff 34(1)(c) (Gwybodaeth Cleifion) rhodder–

"(c) information about the procedure for notifying concerns in accordance with Part 5A or, in respect of complaints made prior to 1 April 2011, the complaints procedure which it operates in accordance with Part 6 giving, in the case of a complaint under Part 6, the name and title of the person nominated in accordance with paragraph 50(2)(a) or, in the case of a notification of a concern, the name of the person designated as the senior investigations manager under regulation 8 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.".

(b) o flaen Rhan 6 (Cwynion) mewnosoder–

"**Part 5A**

Concerns notified on or after 1 April 2011

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.".

(c) yn Rhan 6 (Cwynion)–

(i) yn lle'r pennawd ar gyfer paragraff 47 (Gweithdrefn gwynion), rhodder–

(**1**) O.S. 2006/490 (Cy.59).

"**24**

How patients may–

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 6;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of service.".

Amendment of the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006

4.–(1) The National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(**1**), is amended as follows.

(2) In Schedule 3 (other contractual terms)–

(a) in Part 5 (Records, Information, Notifications and Rights of Entry), for paragraph 34(1)(c) (Patient Information) substitute –

"(c) information about the procedure for notifying concerns in accordance with Part 5A or, in respect of complaints made prior to 1 April 2011, the complaints procedure which it operates in accordance with Part 6 giving, in the case of a complaint under Part 6, the name and title of the person nominated in accordance with paragraph 50(2)(a) or, in the case of a notification of a concern, the name of the person designated as the senior investigations manager under regulation 8 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.".

(b) before Part 6 (Complaints) insert–

"**Part 5A**

Concerns notified on or after 1 April 2011

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.".

(c) in Part 6 (Complaints)–

(i) for the heading relating to paragraph 47 (Complaints procedure), substitute–

(**1**) S.I. 2006/490 (W.59).

"**Complaints received prior to 1 April 2011**";

(ii) ym mharagraff 47 (Gweithdrefn gwynion), yn lle is-baragraff (1), rhodder–

"As regards complaints relating to any matter reasonably connected with the provision of services under the contract which are received before 1 April 2011, the contractor must operate a complaints procedure which complies with the requirements of paragraphs 48 to 50 and 52.";

(iii) ym mharagraff 51 (cydweithredu ag ymchwiliadau)–

(aa) ar ôl "complaint" ym mhob lle y mae'n digwydd, mewnosoder "or concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011"; a

(bb) yn lle is-baragraff (1)(a)(iii) rhodder–

"(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; and"; ac

(ch) yn Rhan 7 (Datrys anghydfodau), ym mharagraff 54 (Datrys anghydfodau: contractau ac eithrio contractau GIG), yn lle'r geiriau "complaints procedure pursuant to Part 6" rhodder "procedures for notifying concerns or making complaints pursuant to Parts 5A or 6".

(3) Yn Atodlen 4 (Taflen Wybodaeth i Gleifion), yn lle paragraff 17 rhodder–

"**17**

How patients may–

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 3;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of a service. ".

Diwygio Rheoliadau'r Gwasanaeth Iechyd Gwladol (Cytundebau Gwasanaethau Deintyddol Personol) (Cymru) 2006

5.–(1) Diwygir Rheoliadau'r Gwasanaeth Iechyd Gwladol (Cytundebau Gwasanaethau Deintyddol Personol) (Cymru) 2006(**1**) fel a ganlyn.

(2) Yn Atodlen 3 (telerau contractiol eraill)–

(a) yn Rhan 5 (Cofnodion, Gwybodaeth, Hysbysiadau a Hawliau Mynediad), yn lle paragraff 35(1)(c) (Gwybodaeth cleifion), rhodder–

(**1**) O.S. 2006/489 (Cy.58).

"**Complaints received prior to 1 April 2011**";

(ii) in paragraph 47 (Complaints procedure), for sub-paragraph (1)–

"As regards complaints relating to any matter reasonably connected with the provision of services under the contract which are received before 1 April 2011, the contractor must operate a complaints procedure which complies with the requirements of paragraphs 48 to 50 and 52.";

(iii) in paragraph 51 (co-operation with investigations)–

(aa) after "complaint" in each place it occurs insert "or concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 "; and

(bb) for sub-paragraph (1)(a)(iii) substitute–

"(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; and"; and

(d) in Part 7 (Dispute resolution), in paragraph 54 (Dispute resolution: non NHS contracts), for "complaints procedure pursuant to Part 6" substitute "procedures for notifying concerns or making complaints pursuant to Parts 5A or 6".

(3) In Schedule 4 (Patient Information Leaflet), for paragraph 17 substitute–

"**17**

How patients may–

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 3;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of a service. ".

Amendment of the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006

5.–(1) The National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(**1**) is amended as follows.

(2) In Schedule 3 (other contractual terms)–

(a) in Part 5 (Records, Information, Notifications and Rights of Entry), for paragraph 35(1)(c) (Patient information) substitute–

(**1**) S.I. 2006/489 (W.58).

"(c) information about the procedure for notifying concerns in accordance with Part 5A or, in respect of complaints made prior to 1 April 2011, the complaints procedure which it operates in accordance with Part 6 giving, in the case of a complaint under Part 6, the name and title of the person nominated in accordance with paragraph 50(2)(a) or, in the case of a notification of a concern, the name of the person designated as the senior investigations manager under regulation 8 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.";

(b) o flaen Rhan 6 (Cwynion) mewnosoder–

"**Part 5A**

Concerns Notified On or After 1 April 2011

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.";

(c) yn Rhan 6 (cwynion)–

(i) yn lle'r pennawd ar gyfer paragraff 47 (Gweithdrefn gwynion) rhodder–

"**Complaints received prior to 1 April 2011**";

(ii) ym mharagraff 47 (Gweithdrefn gwynion), yn is-baragraff (1), yn lle'r geiriau o "The contractor" hyd at "the agreement" rhodder–

"As regards complaints relating to any matter reasonably connected with the provision of services under the agreement which are received before 1 April 2011, the contractor must operate a complaints procedure";

(iii) ym mharagraff 51 (Cydweithredu ag ymchwiliadau)–

(aa) ar ôl "complaint" ym mhob lle y mae'n digwydd, mewnosoder "or concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011"; a

(bb) yn lle is-baragraff (1)(a)(iii) rhodder–

(iv) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales; "; ac

(ch) yn Rhan 7 (Datrys Anghydfodau), ym mharagraff 54 (datrys anghydfodau: contractau ac eithrio contractau GIG), yn lle'r

"(c) information about the procedure for notifying concerns in accordance with Part 5A or, in respect of complaints made prior to 1 April 2011,, the complaints procedure which it operates in accordance with Part 6 giving, in the case of a complaint under Part 6, the name and title of the person nominated in accordance with paragraph 50(2)(a) or, in the case of a notification of a concern, the name of the person designated as the senior investigations manager under regulation 8 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.";

(b) before Part 6 (Complaints) insert–

"**Part 5A**

Concerns Notified On or After 1 April 2011

46A

The contractor must establish and operate arrangements which meet the requirements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 to deal with any concerns notified on or after 1 April 2011 about any matter reasonably connected with the provision of services under the contract.";

(c) in Part 6 (complaints)–

(i) for the heading relating to paragraph 47 (Complaints procedure), substitute–

"**Complaints received prior to 1 April 2011**";

(ii) in paragraph 47 (Complaints procedure), in sub-paragraph (1) for the words from "The contractor" to "the agreement" substitute–

"As regards complaints relating to any matter reasonably connected with the provision of services under the agreement which are received before 1 April 2011, the contractor must operate a complaints procedure";

(iii) in paragraph 51 (Co-operation with investigations)–

(aa) after "complaint" in each place it occurs insert "or concern notified in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011"; and

(bb) for sub-paragraph (1)(a)(iii) substitute–

"(iii) the Welsh Ministers; and

(iv) the Public Services Ombudsman for Wales;"; and

(d) in Part 7 (Dispute Resolution), in paragraph 54 (dispute resolution: non NHS contracts), for "complaints procedure pursuant to Part 6"

geiriau "complaints procedure pursuant to Part 6" rhodder "procedures for notifying concerns or making complaints pursuant to Parts 5A or 6".

(3) Yn Atodlen 4 (Taflen Wybodaeth i Gleifion), yn lle paragraff 16 rhodder–

"**16**

How patients may–

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 3;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of service.".

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substitute "procedures for notifying concerns or making complaints pursuant to Parts 5A or 6".

(3) In Schedule 4 (Patient Information Leaflet), for paragraph 16 substitute–

"**16**

How patients may–

(1) in respect of complaints made prior to 1 April 2011 make a complaint in accordance with the provisions of Part 6 of Schedule 3;

(2) in respect of concerns notified on or after 1 April 2011 notify a concern in accordance with the provisions of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011; or

(3) comment on the provision of service.".

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