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WELSH STATUTORY
INSTRUMENTS

2023 Rhif 274 (Cy. 41)

2023 No. 274 (W. 41)

**Y GWASANAETH IECHYD
GWLADOL, CYMRU**

**NATIONAL HEALTH
SERVICE, WALES**

**Rheoliadau'r Weithdrefn
Dyletswydd Gonestrwydd (Cymru)
2023**

**The Duty of Candour Procedure
(Wales) Regulations 2023**

NODYN ESBONIADOL

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

Mae'r Rheoliadau hyn yn gwneud darpariaeth ynghylch y weithdrefn gonestrwydd sydd i'w dilyn gan gyrff y GIG o dan Ran 3 o Ddeddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020.

Mae rheoliad 2 yn diffinio'r termau a ddefnyddir yn y Rheoliadau hyn.

Mae rheoliad 3 yn gwneud darpariaeth mewn cysylltiad â phwy y mae'n ofynnol i'r corff GIG ei hysbysu a chyfathrebu ag ef o dan y weithdrefn gonestrwydd. Mae'r Rheoliadau hyn yn cyfeirio at y person hwn fel y "person perthnasol", ac yn cyfeirio at y corff GIG y mae arno'r ddyletswydd gonestrwydd i'r person perthnasol fel y "corff cyfrifol".

Mae rheoliad 4(1) yn ei gwneud yn ofynnol i'r corff cyfrifol, wrth ddod yn ymwybodol gyntaf o ganlyniad andwyol hysbysadwy, hysbysu'r person perthnasol dros y ffôn, drwy ddull cyfathrebu clyweledol (megis galwad fideo), neu drwy gyfarfod wyneb yn wyneb. Mae rheoliad 4(3) yn gwneud darpariaeth mewn cysylltiad â'r wybodaeth sydd i'w chynnwys mewn hysbysiad o'r fath.

Mae rheoliad 5 yn ei gwneud yn ofynnol i'r corff cyfrifol ddarparu hysbysiad ysgrifenedig i'r person perthnasol o fewn pum niwrnod gwaith ar ôl dyddiad yr hysbysiad uniongyrchol a ddarperir o dan reoliad 4(1). Mae rheoliad 5(2) yn gwneud darpariaeth ynghylch yr hyn y mae rhaid i'r hysbysiad ysgrifenedig ei gynnwys.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision regarding the candour procedure to be followed by NHS bodies under Part 3 of the Health and Social Care (Quality and Engagement) (Wales) Act 2020.

Regulation 2 defines the terms used within these Regulations.

Regulation 3 makes provision in respect of whom the NHS body is required to notify and communicate with under the candour procedure. These Regulations refer to this person as the "relevant person" and refer to the NHS body that owes the duty of candour to the relevant person as the "responsible body".

Regulation 4(1) requires the responsible body, on first becoming aware of a notifiable adverse outcome, to notify the relevant person by telephone, audio-visual communication (such as a video call), or a face-to-face meeting. Regulation 4(3) makes provision in respect of the information to be included in such notification.

Regulation 5 requires the responsible body to provide written notification to the relevant person within five working days after the in-person notification provided under regulation 4(1). Regulation 5(2) makes provision regarding what the written notification must include.

Mae rheoliad 6 yn ei gwneud yn ofynnol i gorff cyfrifol hysbysu'r person perthnasol am ganlyniadau unrhyw ymholiadau pellach a gynhelir gan y corff mewn cysylltiad â'r amgylchiadau y daeth y ddyletswydd gonestrwydd yn effeithiol odanynt.

Mae rheoliad 7 yn gwneud darpariaeth bellach mewn cysylltiad â chyfathrebu rhwng y corff cyfrifol a'r person perthnasol sy'n ofynnol yn rhinwedd y Rheoliadau hyn.

Mae rheoliad 8 yn ei gwneud yn ofynnol i'r corff cyfrifol ddarparu hyfforddiant a gwybodaeth ynghylch gwasanaethau a all ddarparu cynhorthwy a chymorth i staff.

Mae rheoliad 9 yn darparu bod rhaid i'r corff cyfrifol gadw cofnod ysgrifenedig (sy'n cynnwys cofnod electronig) ar gyfer pob canlyniad andwyol hysbysadwy y dilynir y weithdrefn gonestrwydd mewn cysylltiad ag ef.

Mae rheoliad 10 yn ei gwneud yn ofynnol i'r corff cyfrifol ddynodi person i fod yn gyfrifol am gynnal goruchwyliaeth strategol o'r modd y mae'n gweithredu'r weithdrefn gonestrwydd.

Mae rheoliad 11 yn ei gwneud yn ofynnol i'r corff cyfrifol ddynodi swyddog cyfrifol i gymryd cyfrifoldeb cyffredinol am weithrediad effeithiol y weithdrefn gonestrwydd o ddydd i ddydd ac i sicrhau bod y corff cyfrifol yn cydymffurfio â gofynion y Rheoliadau hyn.

Mae rheoliad 12 yn nodi cyfyngiadau ar ddarparu gwybodaeth.

Mae rheoliad 13 yn darparu nad yw ymddiheuriad, neu gam arall a gymerir yn unol â'r weithdrefn gonestrwydd, yn gyfaddefiad o esgeulustod neu o dorri dyletswydd statudol.

Mae rheoliad 14 yn gwneud diwygiadau i Rheoliadau'r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011 o ganlyniad i'r Rheoliadau hyn.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, lluniwyd asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn. Gellir cael copi oddi wrth: Llywodraeth Cymru, Parc Cathays, Caerdydd, CF10 3NQ ac mae wedi ei gyhoeddi ar www.llyw.cymru.

Regulation 6 requires a responsible body to notify the relevant person of the results of any further enquiries carried out by the body in respect of the circumstances in which the duty of candour came into effect.

Regulation 7 makes further provision in respect of communication between the responsible body and the relevant person required by virtue of these Regulations.

Regulation 8 requires the responsible body to provide training and information about services which can provide assistance and support to staff.

Regulation 9 provides that the responsible body must keep a written record (which includes an electronic record) for each notifiable adverse outcome in respect of which the candour procedure is followed.

Regulation 10 requires the responsible body to designate a person to be responsible for maintaining strategic oversight of its operation of the candour procedure.

Regulation 11 requires the responsible body to designate a responsible officer to take overall responsibility for the effective day to day operation of the candour procedure and to ensure that the responsible body complies with the requirements of these Regulations.

Regulation 12 sets out limitations on the provision of information.

Regulation 13 provides that an apology or other step taken in accordance with the candour procedure is not an admission of negligence or breach of a statutory duty.

Regulation 14 makes amendments to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 in consequence of these Regulations.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on www.gov.wales.

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2023

The Duty of Candour Procedure
(Wales) Regulations 2023

Gwnaed 7 Mawrth 2023
Gosodwyd gerbron Cymru *Senedd*
9 Mawrth 2023
Yn dod i rym 1 Ebrill 2023

Made 7 March 2023
Laid before Senedd Cymru 9 March 2023
Coming into force 1 April 2023

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddir gan adrannau 4, 25(2), 28(1) a (2) o Ddeddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020(1).

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 4, 25(2), 28(1) and (2) of the Health and Social Care (Quality and Engagement) (Wales) Act 2020(1).

Enwi a chychwyn

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Weithdrefn Dyletswydd Gonestrwydd (Cymru) 2023.

(2) Daw'r Rheoliadau hyn i rym ar 1 Ebrill 2023.

Title and commencement

1.—(1) The title of these Regulations is the Duty of Candour Procedure (Wales) Regulations 2023.

(2) These Regulations come into force on 1 April 2023.

Dehongli

2.—(1) Yn y Rheoliadau hyn—

ystyr “Awdurdod Iechyd Arbennig” (“*Special Health Authority*”) yw corff a sefydlwyd o dan adran 22 o Ddeddf 2006; ond nid yw'n cynnwys unrhyw Awdurdod Iechyd Arbennig trawsffiniol (o fewn yr ystyr a roddir i “cross-border Special Health Authority” yn adran 8A(5) o Ddeddf 2006) ac eithrio Gwaed a Thrawsblaniadau'r GIG;

ystyr “Bwrdd Iechyd Lleol” (“*Local Health Board*”) yw corff a sefydlwyd o dan adran 11 o Ddeddf 2006;

Interpretation

2.—(1) In these Regulations—

“the 2006 Act” (“*Deddf 2006*”) means the National Health Service (Wales) Act 2006(2);

“the 2011 Regulations” (“*Rheoliadau 2011*”) means the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011(3);

“the Act” (“*y Ddeddf*”) means the Health and Social Care (Quality and Engagement) (Wales) Act 2020;

(1) 2020 dsc 1.

(1) 2020 asc 1.

(2) 2006 c. 42.

(3) S.I. 2011/704 (W. 108).

mae “canlyniad andwyol hysbysadwy” (“*notifiable adverse outcome*”) yn digwydd pan ddaw’r ddyletswydd gonestrwydd yn effeithiol yn unol ag adran 3 o’r Ddeddf;

ystyr “corff cyfrifol” (“*responsible body*”) yw corff GIG y mae’r ddyletswydd gonestrwydd a osodir gan adran 3 o’r Ddeddf wedi dod yn effeithiol mewn perthynas ag ef;

ystyr “corff GIG” (“*NHS body*”) yw—

- (a) Bwrdd Iechyd Lleol;
- (b) ymddiriedolaeth GIG;
- (c) Awdurdod Iechyd Arbennig;
- (d) darparwr gofal sylfaenol;

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

ystyr “defnyddiwr gwasanaeth” (“*service user*”) yw person, y mae corff GIG yn darparu neu wedi darparu gofal iechyd iddo, sydd wedi dioddef canlyniad andwyol;

ystyr “y Ddeddf” (“*the Act*”) yw Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020;

ystyr “gofal iechyd” (“*health care*”) yw gwasanaethau a ddarperir yng Nghymru o dan neu yn rhinwedd Deddf 2006 ar gyfer neu mewn cysylltiad ag—

- (a) atal salwch, gwneud diagnosis ohono neu ei drin;
- (b) hybu ac amddiffyn iechyd y cyhoedd;

ystyr “gweithdrefn gonestrwydd” (“*candour procedure*”) yw’r weithdrefn a nodir yn y Rheoliadau hyn y mae rhaid i gorff GIG ei dilyn mewn perthynas â chanlyniad andwyol hysbysadwy;

mae “niwed” (“*harm*”) yn cynnwys niwed seicolegol ac, yn achos defnyddiwr gwasanaeth sy’n feichiog, golli neu niweidio’r plentyn heb ei eni;

ystyr “Rheoliadau 2011” (“*the 2011 Regulations*”) yw Rheoliadau’r Gwasanaeth Iechyd Gwladol (Trefniadau Pryderon, Cwynion ac Iawn) (Cymru) 2011(2);

mae i “salwch” yr ystyr a roddir i “illness” yn adran 206 o Ddeddf 2006;

ystyr “ymddiheuriad” (“*apology*”) yw mynegiant o dristwch neu edifeirwch mewn cysylltiad â’r canlyniad andwyol hysbysadwy;

ystyr “ymddiriedolaeth GIG” (“*NHS trust*”) yw corff a sefydlwyd o dan adran 18 o Ddeddf 2006.

“apology” (“*ymddiheuriad*”) means an expression of sorrow or regret in respect of the notifiable adverse outcome;

“candour procedure” (“*gweithdrefn gonestrwydd*”) means the procedure set out in these Regulations that an NHS body must follow in relation to a notifiable adverse outcome;

“harm” (“*niwed*”) includes psychological harm, and in the case of a service user who is pregnant, loss of or harm to the unborn child;

“health care” (“*gofal iechyd*”) means services provided in Wales under or by virtue of the 2006 Act for or in connection with—

- (a) the prevention, diagnosis or treatment of illness;
- (b) the promotion and protection of public health;

“illness” (“*salwch*”) has the meaning given in section 206 of the 2006 Act;

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a body established under section 11 of the 2006 Act;

“NHS body” means—

- (a) a Local Health Board;
- (b) an NHS trust;
- (c) a Special Health Authority;
- (d) a primary care provider;

“NHS trust” (“*ymddiriedolaeth GIG*”) means a body established under section 18 of the 2006 Act;

“notifiable adverse outcome” (“*canlyniad andwyol hysbysadwy*”) occurs when the duty of candour comes into effect in accordance with section 3 of the Act;

“responsible body” (“*corff cyfrifol*”) means an NHS body in relation to which the duty of candour imposed by section 3 of the Act has come into effect;

“service user” (“*defnyddiwr gwasanaeth*”) means a person, to whom health care is being or has been provided by an NHS body, that has suffered an adverse outcome;

“Special Health Authority” (“*Awdurdod Iechyd Arbennig*”) means a body established under section 22 of the 2006 Act; but does not include any cross-border Special Health Authority (within the meaning of section 8A(5) of the 2006 Act) other than NHS Blood and Transplant.

(1) 2006 p. 42.

(2) O.S. 2011/704 (Cy. 108).

(2) Mae person yn ddarparwr gofal sylfaenol, at ddibenion y Rheoliadau hyn, i'r graddau (a dim ond i'r graddau) y mae'r person yn darparu gofal iechyd ar ran Bwrdd Iechyd Lleol yn rhinwedd contract, cytundeb neu drefniant o dan Ran 4, 5, 6 neu 7 o Ddeddf 2006 rhwng y person a'r Bwrdd Iechyd Lleol.

(3) Mae defnyddiwr gwasanaeth i'w drin fel pe bai wedi dioddef canlyniad andwyol os yw'r defnyddiwr yn profi mwy nag ychydig o niwed annisgwyl neu anfriadol neu os yw'r amgylchiadau yn golygu y gallai brofi niwed o'r fath.

(4) Mae gofal iechyd a ddarperir gan un corff GIG (y "corff darparu") ar ran corff GIG arall ("y corff GIG trefnu"), yn rhinwedd contract, cytundeb neu drefniant a wneir o dan Ddeddf 2006 rhwng y corff darparu a'r corff trefnu, i'w drin at ddibenion y Rheoliadau hyn fel pe bai'n cael ei ddarparu gan y corff darparu, nid y corff trefnu.

(5) Mae gofal iechyd a ddarperir gan berson ac eithrio corff GIG (y "darparwr"), ar ran corff GIG, pa un ai yn rhinwedd contract, cytundeb neu drefniant a wneir o dan Ddeddf 2006 neu fel arall, i'w drin at ddibenion y Rheoliadau hyn fel pe bai'n cael ei ddarparu gan y corff GIG, nid y darparwr.

(6) Mae dogfen y mae'n ofynnol iddi fod yn "ysgrifenedig", neu gofnod y mae'n ofynnol iddo fod yn "ysgrifenedig", yn rhinwedd y Rheoliadau hyn yn cynnwys cyfathrebiad electronig, fel y diffinnir "electronic communication" yn adran 15(1) o Ddeddf Cyfathrebiadau Electronig 2000(1).

Person perthnasol

3. Yn y Rheoliadau hyn, ystyr y "person perthnasol" yw—

- (a) y defnyddiwr gwasanaeth, neu
- (b) o ran y defnyddiwr gwasanaeth—
 - (i) os yw wedi marw,
 - (ii) os yw'n 16 oed neu drosodd ac nad yw'r galluedd ganddo (o fewn ystyr Deddf Galluedd Meddyliol 2005(2)) mewn perthynas â'r mater,
 - (iii) os yw o dan 16 oed ac nad yw'n gymwys i wneud penderfyniad mewn perthynas â'i ofal neu ei driniaeth, neu

(2) A person is a primary care provider, for the purposes of these Regulations, in so far as (and only in so far as) the person provides health care on behalf of a Local Health Board by virtue of a contract, agreement or arrangement under Part 4, 5, 6 or 7 of the 2006 Act between the person and the Local Health Board.

(3) A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any unexpected or unintended harm that is more than minimal.

(4) Health care provided by one NHS body (the "providing body") on behalf of another NHS body ("the arranging NHS body"), by virtue of a contract, agreement, or arrangement made under the 2006 Act between the providing body and the arranging body, is to be treated for the purposes of these Regulations as being provided by the providing body, not the arranging body.

(5) Health care provided by a person other than an NHS body (the "provider"), on behalf of an NHS body, whether by virtue of a contract, agreement or arrangement made under the 2006 Act or otherwise, is to be treated for the purposes of these Regulations as being provided by the NHS body, not the provider.

(6) A document or record required by virtue of these Regulations to be "written" includes an electronic communication, as defined in section 15(1) of the Electronic Communications Act 2000(1).

Relevant person

3. In these Regulations the "relevant person" means—

- (a) the service user, or
- (b) if the service user—
 - (i) has died,
 - (ii) is 16 or over and lacks capacity (within the meaning of the Mental Capacity Act 2005(2)) in relation to the matter,
 - (iii) is under 16 and not competent to make a decision in relation to their care or treatment, or

(1) 2000 p. 7; diwygiwyd adran 15(1) gan Ddeddf Cyfathrebiadau 2003 (p. 21).

(2) 2005 p. 9.

(1) 2000 c. 7; section 15(1) was amended by the Communications Act 2003 (c. 21).

(2) 2005 c. 9.

- (iv) os yw wedi rhoi gwybod i'r corff cyfrifol ei fod wedi enwebu person i weithredu ar ei ran,

person sy'n gweithredu ar ran y defnyddiwr gwasanaeth hwnnw.

- (iv) has informed the responsible body that they have nominated a person to act on their behalf,

a person acting on behalf of that service user.

Hysbysiad uniongyrchol

4.—(1) Wrth ddod yn ymwybodol gyntaf o ganlyniad andwyol hysbysadwy, rhaid i gorff cyfrifol hysbysu'r person perthnasol yn unol â'r rheoliad hwn.

(2) Rhaid gwneud hysbysiad o dan baragraff (1) drwy ddefnyddio dull cyfathrebu uniongyrchol.

(3) Rhaid i'r hysbysiad o dan baragraff (1) gynnwys—

- (a) disgrifiad o amgylchiadau'r canlyniad andwyol hysbysadwy, i'r graddau y mae'r corff cyfrifol yn ymwybodol o'r ffeithiau ar y dyddiad y darperir yr hysbysiad i'r person perthnasol,
- (b) y rheswm pam y mae'r corff cyfrifol yn ystyried bod yr amodau a nodir yn adran 3(2) a (3) o'r Ddeddf wedi eu bodloni,
- (c) ymddiheuriad,
- (d) enw a manylion cyswllt y person yn y corff cyfrifol sydd wedi ei enwebu'n bwynt cyswllt ar gyfer y person perthnasol mewn cysylltiad â'r weithdrefn gonestrwydd,
- (e) esboniad o'r camau y bydd y corff cyfrifol neu'r darparwr yn eu cymryd, ac ymholiadau pellach y bydd y corff cyfrifol neu'r darparwr yn eu cynnal, i ymchwilio i amgylchiadau'r canlyniad andwyol hysbysadwy, gan gynnwys unrhyw gamau sydd i'w cymryd o dan Reoliadau 2011,
- (f) manylion unrhyw wasanaethau neu unrhyw gymorth y mae'r corff cyfrifol yn ystyried yn rhesymol y gallant roi cynhorthwy i'r person perthnasol, gan ystyried anghenion y person perthnasol, ac
- (g) pan fo'r hysbysiad o dan baragraff (1) yn cael ei wneud yn hwyrach na 30 o ddiwrnodau gwaith ar ôl i'r corff cyfrifol ddod yn ymwybodol gyntaf o'r canlyniad andwyol hysbysadwy, esboniad o'r rheswm dros yr oedi.

(4) Yn y rheoliad hwn, ystyr “cyfathrebu uniongyrchol” yw cyfathrebu sy'n digwydd drwy alwad ffôn, drwy gyfathrebu clyweledol, neu drwy gyfarfod wyneb yn wyneb.

In-person notification

4.—(1) On first becoming aware of a notifiable adverse outcome, a responsible body must notify the relevant person in accordance with this regulation.

(2) Notification under paragraph (1) must be by in-person communication.

(3) The notification under paragraph (1) must include—

- (a) an account of the circumstances of the notifiable adverse outcome, in so far as the responsible body is aware of the facts at the date the notification is provided to the relevant person,
- (b) the reason that the responsible body considers that the conditions set out in section 3(2) and (3) of the Act have been met,
- (c) an apology,
- (d) the name and contact details of the person at the responsible body nominated as the point of contact for the relevant person in respect of the candour procedure,
- (e) an explanation of the actions that the responsible body or the provider will take, and further enquiries that the responsible body or the provider will carry out, to investigate the circumstances of the notifiable adverse outcome, including any actions to be taken under the 2011 Regulations,
- (f) details of any services or support which the responsible body reasonably considers may provide assistance to the relevant person, taking into account the relevant person's needs, and
- (g) where the notification under paragraph (1) is made later than 30 working days after the responsible body first became aware of the notifiable adverse outcome, an explanation of the reason for the delay.

(4) In this regulation, “in-person communication” means communication that is made by telephone call, audio-visual communication or a face-to-face meeting.

Hysbysiad ysgrifenedig

5.—(1) Rhaid i'r corff cyfrifol hysbysu'r person perthnasol yn ysgrifenedig yn unol â'r rheoliad hwn.

(2) Rhaid i'r corff cyfrifol gymryd pob cam rhesymol i anfon yr hysbysiad ysgrifenedig o dan baragraff (1) at y person perthnasol o fewn pum niwrnod gwaith ar ôl y dyddiad y mae'r corff cyfrifol yn hysbysu'r person perthnasol o dan reoliad 4(1).

(3) Rhaid i'r hysbysiad ysgrifenedig o dan baragraff (1) gynnwys—

- (a) disgrifiad o unrhyw ystyriaeth gychwynnol o'r canlyniad andwyol hysbysadwy,
- (b) ymddiheuriad, ac
- (c) yr wybodaeth a ddarperir o dan reoliad 4(3)(b), 4(3)(d), 4(3)(e), 4(3)(f) ac, os yw'n berthnasol, 4(3)(g).

Hysbysiad am ganlyniadau ymholiadau pellach

6. Rhaid i'r corff cyfrifol hysbysu'r person perthnasol am ganlyniadau unrhyw ymholiadau pellach y cyfeirir atynt yn rheoliad 4(3)(e).

Cyfathrebu â'r person perthnasol

7.—(1) Rhaid i'r corff cyfrifol gymryd camau rhesymol i ganfod y dull cyfathrebu a ffeirir gan y person perthnasol a, phan fo'n rhesymol ymarferol, gyfathrebu â'r person perthnasol gan ddefnyddio'r dull hwn.

(2) Rhaid i'r corff cyfrifol gymryd camau rhesymol i sicrhau bod unrhyw gyfathrebu â'r person perthnasol yn digwydd mewn modd y gall y person perthnasol ei ddeall.

(3) Os na all y corff cyfrifol gysylltu â'r person perthnasol, ar ôl cymryd camau rhesymol i wneud hynny, i roi hysbysiad o dan unrhyw un neu ragor o reoliadau 4, 5 neu 6, neu os yw'r person perthnasol yn gwrthod cyfathrebu â'r corff cyfrifol—

- (a) rhaid i'r corff cyfrifol sicrhau bod y cofnod a gedwir o dan reoliad 9 yn cynnwys gwybodaeth am bob ymgais a wnaed i gysylltu â'r person perthnasol neu i gyfathrebu ag ef, a
- (b) mae rheoliadau 4, 5 a 6 yn peidio â bod yn gymwys.

Hyfforddiant a chymorth

8.—(1) Rhaid i'r corff cyfrifol sicrhau bod yr aelodau o staff a bennir ym mharagraff (2) yn cael hyfforddiant ac arweiniad perthnasol ynghylch y weithdrefn gonestrwydd.

Written notification

5.—(1) The responsible body must notify the relevant person in writing in accordance with this regulation.

(2) The responsible body must take all reasonable steps to send the written notification under paragraph (1) to the relevant person within five working days after the date that the responsible body notifies the relevant person under regulation 4(1).

(3) The written notification under paragraph (1) must include—

- (a) a description of any initial consideration of the notifiable adverse outcome,
- (b) an apology, and
- (c) the information provided under regulation 4(3)(b), 4(3)(d), 4(3)(e), 4(3)(f) and, if relevant, 4(3)(g).

Notification of results of further enquiries

6. The responsible body must notify the relevant person of the results of any further enquiries referred to in regulation 4(3)(e).

Communication with relevant person

7.—(1) The responsible body must take reasonable steps to ascertain the relevant person's preferred method of communication and, where reasonably practicable, communicate with the relevant person by this method.

(2) The responsible body must take reasonable steps to ensure any communication with the relevant person is in a manner that the relevant person can understand.

(3) If the responsible body, having taken reasonable steps, is unable to contact the relevant person to give notification under any of regulations 4, 5 or 6, or the relevant person declines to communicate with the responsible body—

- (a) the responsible body must ensure that the record kept under regulation 9 includes information about the attempts made to contact or to communicate with the relevant person, and
- (b) regulations 4, 5 and 6 cease to apply.

Training and support

8.—(1) The responsible body must ensure that the members of staff specified in paragraph (2) receive relevant training and guidance on the candour procedure.

(2) At ddibenion paragraff (1), yr aelodau o staff yw—

- (a) y rheini sy'n ymwneud â darparu gofal iechyd;
- (b) y rheini sy'n ymwneud ag ymchwilio i ganlyniadau andwyol hysbysadwy neu eu rheoli;
- (c) unrhyw aelodau perthnasol eraill o staff sy'n ymwneud â chyflawni neu arfer swyddogaethau mewn cysylltiad â'r weithdrefn gonestrwydd.

(3) Rhaid i'r corff cyfrifol ddarparu i aelod o staff sy'n ymwneud â chanlyniad andwyol hysbysadwy fanylion unrhyw wasanaethau y mae'r corff cyfrifol yn ymwybodol ohonynt a all roi cynhorthwy neu gymorth i'r aelod hwnnw o staff, gan ystyried—

- (a) yr amgylchiadau sy'n ymwneud â'r canlyniad andwyol hysbysadwy, a
- (b) anghenion yr aelod o staff.

(4) Yn y rheoliad hwn, "aelod o staff" yw unrhyw berson sy'n gweithio i gorff GIG, pa un ai o dan gontract cyflogaeth, contract am wasanaethau neu fel gwirfoddolwr, neu weithwyr asiantaeth (o fewn yr ystyr a roddir i "agency workers" yn rheoliad 3 o Reoliadau Gweithwyr Asiantaeth 2010(1)) sy'n gweithio o dan oruchwyliaeth a chyfarwyddyd corff GIG.

Cofnodion

9.—(1) Rhaid i'r corff cyfrifol gadw cofnod ysgrifenedig ar gyfer pob canlyniad andwyol hysbysadwy y dilynir y weithdrefn gonestrwydd mewn cysylltiad ag ef.

(2) Rhaid i'r cofnod sy'n ofynnol gan baragraff (1) gynnwys pob dogfen a phob darn o ohebiaeth sy'n ymwneud â'r canlyniad andwyol hysbysadwy, gan gynnwys ond heb fod yn gyfyngedig i—

- (a) cofnodion o hysbysiadau a roddir o dan reoliadau 4, 5 a 6,
- (b) cofnodion o bob ymgais i gysylltu â'r person perthnasol,
- (c) unrhyw benderfyniad gan y person perthnasol nad yw am i neb gysylltu ag ef mewn perthynas â'r weithdrefn gonestrwydd, a
- (d) pob dogfen sy'n ymwneud â'r ymchwiliad i'r canlyniad andwyol hysbysadwy a'r adolygiad o'r canlyniad andwyol hysbysadwy a gynhelir gan y corff cyfrifol, gan gynnwys unrhyw ymatebion neu adroddiadau interim a ddyroddir gan y corff cyfrifol o dan reoliad 24, 26 neu 31 o Reoliadau 2011.

(2) For the purposes of paragraph (1), the members of staff are—

- (a) those involved in the provision of health care;
- (b) those involved in investigating or managing notifiable adverse outcomes;
- (c) any other relevant members of staff who are involved in performing or exercising functions in connection with the candour procedure.

(3) The responsible body must provide a member of staff who is involved in a notifiable adverse outcome with details of any services of which the responsible body is aware which may provide assistance or support to any such member of staff, taking into account—

- (a) the circumstances relating to the notifiable adverse outcome, and
- (b) the member of staff's needs.

(4) In this regulation, a "member of staff" is any person who works for an NHS body, whether under a contract of employment, a contract for services or as a volunteer, or agency workers (within the meaning of regulation 3 of the Agency Workers Regulations 2010(1)) working under the supervision and direction of an NHS body.

Records

9.—(1) The responsible body must keep a written record for each notifiable adverse outcome in respect of which the candour procedure is followed.

(2) The record required by paragraph (1) must include every document and piece of correspondence relating to the notifiable adverse outcome, including but not limited to—

- (a) records of notifications given under regulations 4, 5 and 6,
- (b) records of attempts to contact the relevant person,
- (c) any decision by the relevant person not to be contacted in relation to the candour procedure, and
- (d) all documentation relating to the investigation and review of the notifiable adverse outcome undertaken by the responsible body, including any responses or interim reports issued by the responsible body under regulation 24, 26 or 31 of the 2011 Regulations.

(1) O.S. 2010/93, a ddiwygiwyd gan O.S. 2011/1941.

(1) S.I. 2010/93, amended by S.I. 2011/1941.

Goruchwyliaeth strategol o'r weithdrefn gonestrwydd

10.—(1) Rhaid i bob corff cyfrifol ddynodi person i fod yn gyfrifol am gynnal goruchwyliaeth strategol o'r modd y mae'n gweithredu'r weithdrefn gonestrwydd.

(2) Pan fo'r corff cyfrifol yn Fwrdd Iechyd Lleol, yn Ymddiriedolaeth GIG neu'n Awdurdod Iechyd Arbennig, rhaid i'r person hwnnw fod yn un o'i aelodau nad ydynt yn swyddogion neu'n un o'i gyfarwyddwyr anweithredol, fel y bo'n briodol.

Swyddog cyfrifol

11.—(1) Rhaid i bob corff cyfrifol ddynodi person (y "swyddog cyfrifol") i gymryd cyfrifoldeb cyffredinol am weithrediad effeithiol y weithdrefn gonestrwydd o ddydd i ddydd, ac yn benodol i sicrhau bod y corff cyfrifol yn cydymffurfio â gofynion y Rheoliadau hyn.

(2) Rhaid i'r swyddog cyfrifol—

- (a) yn achos Bwrdd Iechyd Lleol, Ymddiriedolaeth GIG neu Awdurdod Iechyd Arbennig, fod yn berson sy'n swyddog-aelod neu'n gyfarwyddwr gweithredol yn y corff hwnnw, fel y bo'n briodol;
- (b) yn achos darparwr gofal sylfaenol, fod y person sy'n gweithredu fel prif swyddog gweithredol y corff hwnnw neu, os nad oes un—
 - (i) y person sy'n unig berchennog ar y corff cyfrifol;
 - (ii) pan fo'r corff cyfrifol yn bartneriaeth, yn bartner;
 - (iii) mewn unrhyw achos arall, yn un o gyfarwyddwyr y corff cyfrifol, neu'n berson sy'n gyfrifol am reoli'r corff cyfrifol.

(3) 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 ei ran ar yr amod bod y person a awdurdodir felly o dan reolaeth a goruchwyliaeth uniongyrchol y swyddog cyfrifol.

Cyfyngiadau ar ddarparu gwybodaeth

12. Nid yw'r Rheoliadau hyn yn caniatáu nac yn ei gwneud yn ofynnol i gorff cyfrifol ddatgelu unrhyw wybodaeth—

- (a) a fyddai'n rhagfarnu unrhyw ymchwiliad neu erlyniad troseddol, neu

Strategic oversight of the candour procedure

10.—(1) Each responsible body must designate a person to be responsible for maintaining a strategic oversight of its operation of the candour procedure.

(2) Where the responsible body is a Local Health Board, an NHS Trust or a Special Health Authority, that person must be one of its non-officer members or non-executive directors, as appropriate.

Responsible officer

11.—(1) Each responsible body must designate a person (the "responsible officer") to take overall responsibility for the effective day-to-day operation of the candour procedure, and in particular to ensure that the responsible body complies with the requirements of these Regulations.

(2) The responsible officer must be—

- (a) in the case of a Local Health Board, NHS Trust or Special Health Authority, a person who is an officer member or executive director of that body, as appropriate;
- (b) in the case of a primary care provider, 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;
 - (iii) in any other case, a director of the responsible body, or a person who is responsible for managing the responsible body.

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

Limitations on provision of information

12. These Regulations do not permit or require a responsible body to disclose any information which—

- (a) would prejudice any criminal investigation or prosecution, or

- (b) a fyddai'n mynd yn groes i unrhyw gyfyngiad ar ddatgelu sy'n codi yn rhinwedd deddfiad neu reol gyfreithiol.

- (b) would contravene any restriction on disclosure arising by virtue of an enactment or rule of law.

Ymddiheuriad

13. Nid yw ymddiheuriad neu gam arall a gymerir yn unol â'r weithdrefn gonestrwydd yn gyfystyr â chyfaddefiad o esgeulustod neu o dorri dyletswydd statudol.

Apology

13. An apology or other step taken in accordance with the candour procedure does not amount to an admission of negligence or a breach of a statutory duty.

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

14.—(1) Mae Rheoliadau 2011 wedi eu diwygio fel a ganlyn.

(2) Yn rheoliad 2(1) (dehongli), yn y lleoedd priodol mewnoder—

“ystyr “Deddf 2020” (“*the 2020 Act*”) yw Deddf Iechyd a Gofal Cymdeithasol (Ansawdd ac Ymgysylltu) (Cymru) 2020;”;

“ystyr “Rheoliadau 2023” (“*the 2023 Regulations*”) yw Rheoliadau'r Weithdrefn Dyletswydd Gonestrwydd (Cymru) 2023;”.

(3) Yn lle rheoliad 12(7) (personau y caniateir iddynt hysbysu pryderon), rhodder—

“(7) Pan hysbysir pryder gan aelod o staff y corff cyfrifol, rhaid i'r corff cyfrifol, pan fo ei ymchwiliad dechreuol yn canfod bod niwed cymedrol neu ddifrifol neu farwolaeth wedi digwydd—

(a) oni bai bod hysbysiad o dan reoliad 4(1) o Reoliadau 2023 eisoes wedi ei roi, hysbysu'r claf y mae'r pryder yn gysylltiedig ag ef, neu ei gynrychiolydd, am yr hysbysiad o bryder, a

(b) oni bai bod paragraff (8) yn gymwys, gynnwys y claf, neu ei gynrychiolydd, yn yr ymchwiliad i'r pryder,

yn unol â Rhan 5.”

(4) Yn rheoliad 12(8) (personau y caniateir iddynt hysbysu pryderon), hepgorer “pe rhoddid gwybod i'r claf am y pryder, neu”.

(5) Yn rheoliad 22 (y weithdrefn cyn ymchwilio)—

(a) ym mharagraff (1), yn lle “dau ddiwrnod” rhodder “phum niwrnod”;

(b) ar ddechrau paragraff (6), yn lle “Rhaid” rhodder “Yn ddarostyngedig i baragraff (7), rhaid”;

Amendment of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

14.—(1) The 2011 Regulations are amended as follows.

(2) In regulation 2(1) (interpretation) at the appropriate places insert—

““the 2020 Act” (“*Deddf 2020*”) means the Health and Social Care (Quality and Engagement) (Wales) Act 2020;”;

““the 2023 Regulations” (“*Rheoliadau 2023*”) means the Duty of Candour Procedure (Wales) Regulations 2023;”.

(3) For regulation 12(7) (persons who may notify concerns), substitute—

“(7) 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—

(a) unless notification under regulation 4(1) of the 2023 Regulations has already been given, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern, and

(b) unless paragraph (8) applies, involve the patient, or his or her representative, in the investigation of the concern,

in accordance with Part 5.”

(4) In regulation 12(8) (persons who may notify concerns), omit “informed of or”.

(5) In regulation 22 (procedure before investigation)—

(a) in paragraph (1) for “two” substitute “five”;

(b) at the beginning of paragraph (6), for “The” substitute “Subject to paragraph (7), the”;

(c) ar ôl paragraff (6) mewnosoder—

“(7) Pan fo’r ddyletswydd gonestrwydd o dan adran 3 o Ddeddf 2020 wedi dod yn effeithiol mewn perthynas â thestun y pryder a phan fo hysbysiad o dan reoliadau 4(1) a 5(1) o Reoliadau 2023 wedi ei roi, nid yw’n ofynnol i’r corff cyfrifol anfon copi o’r hysbysiad o’r pryder at y claf neu ei gynrychiolydd.”

(c) after paragraph (6) insert—

“(7) Where the duty of candour under section 3 of the 2020 Act has come into effect in relation to the subject matter of the concern and notification under regulations 4(1) and 5(1) of the 2023 Regulations has been given, the responsible body is not required to send a copy of the notification of the concern to the patient or his or her representative.”

Eluned Morgan

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol,
un o Weinidogion Cymru
7 Mawrth 2023

Minister for Health and Social Services, one of the
Welsh Ministers
7 March 2023

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