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OFFERYNNAU STATUDOL  
CYMRU

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**2011 Rhif 734 (Cy.112)**

**IECHYD Y CYHOEDD,  
CYMRU**

**Rheoliadau Gofal Iechyd  
Annibynnol (Cymru) 2011**

**NODYN ESBONIADOL**

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

Gwneir y Rheoliadau hyn o dan Ddeddf Safonau Gofal 2000 ("y Ddeddf") ac maent yn gymwys i ysbytai annibynnol, clinigau annibynnol ac asiantaethau meddygol annibynnol yng Nghymru. Mewn perthynas â Chymru mae'r Ddeddf yn darparu ar gyfer cofrestru ac arolygu sefydliadau ac asiantaethau, gan gynnwys sefydliadau gofal iechyd annibynnol, gan Weinidogion Cymru ac yn galluogi Gweinidogion Cymru i wneud rheoliadau sy'n llywodraethu'r modd y cynhelir sefydliadau ac asiantaethau o'r fath.

Mae adran 2 o'r Ddeddf yn diffinio nifer o "gwasanaethau rhestredig" ("listed services") sydd (os darperir hwy mewn sefydliad) yn gosod y sefydliad o fewn y diffiniad o ysbyty annibynnol. Mae rheoliad 3 yn darparu bod y "gwasanaethau rhestredig" yn cynnwys triniaeth gan ddefnyddio'r technegau a thechnolegau rhagnodedig a bennir yn rheoliad 3(1). Mae rheoliad 3(2) wedyn yn eithrio technegau a thechnolegau penodol rhag bod yn "wasanaethau rhestredig", sef triniaethau penodol â gwres is-goch, triniaethau laser penodol a defnyddio lampau uwchfioled i gael lliw haul artiffisial. Mae rheoliad 3(3) yn eithrio sefydliadau penodol o'r diffiniad o ysbyty annibynnol o dan adran 2 o'r Ddeddf. Ymhlith yr eithriadau hynny mae unrhyw sefydliadau sy'n darparu triniaeth feddygol neu seiciatrig neu ofal lliniarol ond sydd heb welyau dros nos i gleifion, sefydliadau sy'n ysbytai i'r lluoedd arfog yn yr ystyr a roddir i "service hospital" o dan Ddeddf Lluoedd Arfog 2006, neu sy'n darparu ar gyfer tramgwyddwyr o dan Ddeddf Carchardai 1952. Yn ychwanegol, eithrir sefydliadau lle mae ymarferwyr cyffredinol yn darparu gwasanaethau GIG, ond lle y gall lleiafrif bychan o

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WELSH STATUTORY  
INSTRUMENTS

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**2011 No. 734 (W.112)**

**PUBLIC HEALTH, WALES**

**The Independent Health Care  
(Wales) Regulations 2011**

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations are made under the Care Standards Act 2000 ("the Act") and apply to independent hospitals, independent clinics and independent medical agencies in Wales. The Act provides in relation to Wales for the registration and inspection of establishments and agencies, including independent health care establishments, by the Welsh Ministers and empowers the Welsh Ministers to make regulations governing their conduct.

Section 2 of the Act defines a number of "listed services" which (if they are provided in an establishment) bring an establishment within the definition of an independent hospital. Regulation 3 provides that "listed services" include treatment using the prescribed techniques and technology set out in regulation 3(1). Regulation 3(2) then excepts certain techniques and technology from being "listed services", namely certain infra-red heat treatments, certain laser treatments and the use of ultra violet lamps for acquiring an artificial sun tan. Regulation 3(3) excludes certain establishments from the definition of an independent hospital under section 2 of the Act. The exceptions include establishments providing medical or psychiatric treatment or palliative care but which have no overnight beds for patients, establishments which are service hospitals under the Armed Forces Act 2006, or which are establishments catering for offenders under the Prison Act 1952. In addition, establishments where general practitioners provide NHS services, but where there may be a small minority of private patients who also receive treatment are excluded. The private residence of a patient is also

gleifion preifat gael triniaeth hefyd. Mae preswylfa breifat claf hefyd wedi ei heithrio, os y claf hwnnw yw'r unig un y darperir triniaeth iddo yno. Eithrir hefyd unrhyw feddygfeydd ac ystafelloedd ymgynghori (os ydynt ar wahân i ysbyty) lle y darperir gwasanaethau meddygol o dan drefniadau a wnaed ar ran cleifion gan eu cyflogwyr neu gan eraill, yn ogystal â meysydd chwarae a champfeydd lle y rhoddir triniaeth i rai sy'n cymryd rhan mewn gweithgareddau a digwyddiadau chwaraeon. Eithrir sefydliadau sy'n cyflawni gweithdrefnau podiatrig neu fân weithdrefnau ar y croen o dan anesthetig lleol, rhag eu cofrestru fel ysbytai annibynnol.

Mae rheoliad 3(4) yn darparu diffiniad o anesthetig lleol. Mae rheoliad 3(5) yn addasu adran 2(7) o'r Ddeddf i gael effaith fel petai'r geiriau "intravenously administered" wedi eu mewnosod ar ôl y gair "or" yn adran 2(7)(a).

Mae rheoliad 4 yn diffinio ystyr y term "clinig annibynnol".

Mae rheoliad 5 yn eithrio rhai ymgymeriadau o'r diffiniad o asiantaeth feddygol annibynnol.

Gwneir yn ofynnol bod gan bob sefydliad ac asiantaeth ddatganiad o ddiben, sy'n cynnwys y materion a bennir yn Atodlen 1, ynghyd ag arweiniad i'r sefydliad neu'r asiantaeth ar gyfer cleifion, a rhaid cadw'r dogfennau hynny dan arolwg (rheoliadau 6 i 8). Yn rhinwedd rheoliad 6(3) rhaid rhedeg y sefydliad neu'r asiantaeth mewn modd sy'n gyson â'r datganiad o ddiben.

Mae rheoliad 9 yn nodi'r polisiau a'r gweithdrefnau y mae'n rhaid eu paratoi a'u gweithredu mewn perthynas â sefydliad neu asiantaeth.

Mae rheoliadau 10 i 14 yn gwneud darpariaeth ynglŷn â ffitrwydd y personau sy'n rhedeg ac yn rheoli sefydliad neu asiantaeth ac yn ei gwneud yn ofynnol bod gwybodaeth lawn a boddhaol ar gael mewn perthynas â'r materion a ragnodir yn Atodlen 2. Os yw'r darparwr yn gorff, rhaid iddo enwebu unigolyn cyfrifol, y bydd rhaid i'r wybodaeth honno fod ar gael mewn perthynas ag ef (rheoliad 10). Mae rheoliadau 11 a 12 yn rhagnodi o dan ba amgylchiadau y mae'n rhaid penodi rheolwr ar gyfer sefydliad neu asiantaeth ac yn rhagnodi gofynion o ran ffitrwydd y rheolwr. Mae rheoliad 13 yn pennu gofynion cyffredinol mewn perthynas â'r dull priodol o redeg sefydliad neu asiantaeth a'r angen am hyfforddiant priodol. Mae rheoliad 14 yn ei gwneud yn ofynnol i hysbysu swyddfa briodol yr awdurdod cofrestru ynghylch tramgwyddau a chyhuddiadau o dramgwyddau penodol.

Mae Rhan III o'r Rheoliadau yn gwneud darpariaeth ynglŷn â rhedeg sefydliadau ac asiantaethau, sef yn benodol ynglŷn ag ansawdd y gwasanaethau sydd i'w

excluded provided that treatment is provided there only to that patient. There are also excluded surgeries and consulting rooms (which are separate from a hospital) which provide medical services under arrangements made on behalf of patients by their employers or others, and sports grounds and gymnasia where treatment is given to those taking part in sporting activities and events. Establishments which carry out podiatric procedures or minor skin procedures under local anaesthetic are excluded from registration as independent hospitals.

Regulation 3(4) provides a definition of local anaesthetic. Regulation 3(5) modifies section 2(7) of the Act so that the effect is as if the words "intravenously administered" were inserted after "or" in section 2(7)(a).

Regulation 4 defines the meaning of the term "independent clinic".

Regulation 5 excepts certain undertakings from the definition of an independent medical agency.

Each establishment and agency must have a statement of purpose consisting of the matters set out in Schedule 1 and a patients' guide to the establishment or agency which must be kept under review (regulations 6 to 8). By virtue of regulation 6(3) the establishment or agency must be carried on in a manner which is consistent with the statement of purpose.

Regulation 9 sets out the policies and procedures which must be prepared and implemented in relation to an establishment or agency.

Regulations 10 to 14 make provision about the fitness of the persons carrying on and managing an establishment or agency and require full and satisfactory information to be available in relation to the matters prescribed in Schedule 2. Where the provider is an organisation, it must nominate a responsible individual in respect of whom this information must be available (regulation 10). Regulations 11 and 12 prescribe the circumstances where a manager must be appointed for the establishment or agency and for the fitness requirements of a manager. Regulation 13 imposes general requirements in relation to the proper conduct of an establishment or agency and the need for appropriate training. Regulation 14 requires offences and being charged for certain offences to be notified to the appropriate office of the registration authority.

Part III of the Regulations makes provision about the conduct of establishments and agencies, in particular about the quality of the services to be provided in an

darparu mewn sefydliad neu at ddibenion asiantaeth, gan gynnwys materion ynglŷn ag ansawdd triniaeth, preifatrwydd, urddas a defodau crefyddol y cleifion, staffio'r sefydliad neu asiantaeth, addasrwydd y gweithwyr, diogelu cleifion ac ynghylch cwynion, datganiadau blynyddol a chadw cofnodion. Gwneir darpariaeth hefyd ynghylch addasrwydd mangreoedd a'r rhagofalon tân sydd i'w gweithredu ac ynghylch rheolaeth sefydliadau ac asiantaethau. Gwneir darpariaeth benodol mewn perthynas ag ysbytai annibynnol sy'n lletya cleifion sydd ag anableddau dysgu (rheoliad 27). Gwneir yn ofynnol bod darparwr cofrestredig sefydliad yn ymweld â'r sefydliad fel a ragnodir (rheoliad 28) ac mae rheoliad 29 yn pennu gofynion ynghylch hyfywedd ariannol y sefydliad neu asiantaeth. Mae rheoliadau 30 i 35 yn ymdrin â rhoi hysbysiadau i'r awdurdod cofrestru ynglŷn â digwyddiadau penodol megis marwolaeth neu anaf difrifol i glaf; absenoldeb diawdurdod claf a gedwir yn gaeth neu sy'n agored i'w gaethiwo o dan Ddeddf Iechyd Meddwl 1983; absenoldeb rheolwr o'r sefydliad neu'r asiantaeth; rhai newidiadau penodol megis newid person cofrestredig a phersonél eraill, neu newidiadau sylweddol i'r fangre; penodi diddymwyr ac eraill a marwolaeth y person cofrestredig.

Mae Rhan IV ac Atodlen 4 yn pennu gofynion ychwanegol sy'n gymwys i ysbytai annibynnol mewn perthynas â gwasanaethau patholeg, dadebru, trin plant, gweithdrefnau llawfeddygol penodol, triniaeth ddeintyddol, gwasanaethau obstetrig, terfyniadau beichiogrwydd, defnyddio technegau a thechnolegau penodol ac ysbytai annibynnol sy'n darparu gwasanaethau iechyd meddwl.

Mae Rhan V (rheoliad 50) yn cynnwys gofynion ychwanegol pan fo clinig annibynnol yn darparu gofal cynenedigol.

Mae Rhan VI yn ymdrin â materion amrywiol. Yn benodol, mae rheoliad 52 yn darparu ar gyfer tramgwyddau. Ceir dyfarnu bod toriad o reoliadau 6 i 17, 18(1), 19 i 35, 37 i 45 a 47 i 50 yn dramgwydd ar ran y person cofrestredig. Mae rheoliad 53 yn darparu darpariaethau trosiannol mewn perthynas â chymhwyso rheoliad 27 a rhai personau a gofrestrwyd cyn 1 Ebrill 2011. Mae rheoliad 54 yn dirymu Rheoliadau Gofal Iechyd Preifat a Gwirfoddol (Cymru) 2002 ond yn arbed rheoliad 3(4) o'r rheoliadau hynny. Mae hyn yn cadw'r addasiad i adran 2(7)(e) o'r Ddeddf (cyfeiriad at lawdriniaeth gosmetig).

establishment or for the purposes of an agency, including matters relating to the quality of treatment, privacy, dignity and religious observance of patients, the staffing of the establishment or agency, the suitability of workers, safeguarding patients and about complaints, annual returns and record keeping. Provision is also made about the suitability of premises and the fire precautions to be taken and the management of establishments and agencies. Specific provision is made with regard to independent hospitals accommodating patients with learning disabilities (regulation 27). The registered provider is required to visit an establishment as prescribed (regulation 28) and regulation 29 imposes requirements relating to the financial viability of the establishment or agency. Regulations 30 to 35 deal with the giving of notices to the registration authority when certain events occur such as the death or serious injury of a patient; the unauthorised absence of a patient who is detained or liable to be detained under the Mental Health Act 1983; in the case of a manager's absence from the establishment or agency; where certain changes occur, for example, a change in the registered person and other personnel or significant changes to the premises; where liquidators and others are appointed and where the registered person dies.

Part IV and Schedule 4 sets out additional requirements that apply to independent hospitals in relation to pathology services, resuscitation, the treatment of children, certain surgical procedures, dental treatment, obstetric services, terminations of pregnancy, the use of certain techniques and technologies and independent hospitals providing mental health services.

Part V (regulation 50) contains additional requirements where antenatal care is provided by an independent clinic.

Part VI deals with miscellaneous matters. In particular, regulation 52 provides for offences. A breach of regulations 6 to 17, 18(1), 19 to 35, 37 to 45 and 47 to 50 may found an offence on the part of the registered person. Regulation 53 provides transitional provisions relating to the application of regulation 27 and certain persons registered prior to 1 April 2011. Regulation 54 revokes the Private and Voluntary Health Care (Wales) Regulations 2002 but saves regulation 3(4) of those regulations. This retains the modification to section 2(7)(e) of the Act (reference to cosmetic surgery).

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**IECHYD Y CYHOEDD,  
CYMRU**

**PUBLIC HEALTH, WALES**

**Rheoliadau Gofal Iechyd  
Annibynnol (Cymru) 2011**

**The Independent Health Care  
(Wales) Regulations 2011**

*Gwnaed* 10 Mawrth 2011

*Made* 10 March 2011

*Gosodwyd gerbron Cynulliad  
Cenedlaethol Cymru* 14 Mawrth 2011

*Laid before the National  
Assembly for Wales* 14 March 2011

*Yn dod i rym* 5 Ebrill 2011

*Coming into force* 5 April 2011

TREFN Y RHEOLIADAU  
RHAN I – CYFFREDINOL

ARRANGEMENT OF REGULATIONS  
PART 1 – GENERAL

1. Enwi, cychwyn a chymhwyso
2. Dehongli
3. Ystyr "ysbyty annibynnol"
4. Ystyr "clinig annibynnol"
5. Eithrio ymgymeriad o'r diffiniad o asiantaeth feddygol annibynnol
6. Datganiad o ddiben
7. Arweiniad y cleifion
8. Adolygu'r datganiad o ddiben ac arweiniad y cleifion
9. Polisiâu a gweithdrefnau

1. Title, commencement and application
2. Interpretation
3. Meaning of "independent hospital"
4. Meaning of "independent clinic"
5. Exception of undertaking from the definition of independent medical agency
6. Statement of purpose
7. Patients' guide
8. Review of statement of purpose and patients' guide
9. Policies and procedures

RHAN II – PERSONAU COFRESTREDIG

PART II – REGISTERED PERSONS

10. Ffitrwydd y darparwr cofrestredig
11. Penodi rheolwr
12. Ffitrwydd y rheolwr
13. Y person cofrestredig – gofynion cyffredinol
14. Hysbysu ynghylch tramgwyddau

10. Fitness of registered provider
11. Appointment of manager
12. Fitness of manager
13. Registered person – general requirements
14. Notification of offences

RHAN III – RHEDEG SEFYDLIADAU AC  
ASiantaethau Gofal Iechyd

PART III – CONDUCT OF HEALTH CARE  
ESTABLISHMENTS AND AGENCIES

Pennod 1

Chapter 1

- Ansawdd y gwasanaeth a ddarperir
15. Ansawdd y driniaeth a'r gwasanaethau eraill a ddarperir

- Quality of service provision
15. Quality of treatment and other service provision

16. Diogelu cleifion rhag eu cam-drin
17. Galluedd cleifion
18. Preifatrwydd, urddas a pherthnasau
19. Asesu a monitro ansawdd y ddarpariaeth o wasanaethau, gan gynnwys datganiadau blynyddol
20. Staffio
21. Ffitrwydd y gweithwyr
22. Canllawiau ar gyfer proffesiynolion gofal iechyd
23. Cofnodion
24. Cwynion
25. Ymchwil

#### Pennod 2

##### Mangreuedd

26. Ffitrwydd y fangre
27. Ffitrwydd y fangre – anabledd dysgu

#### Pennod 3

##### Rheolaeth

28. Ymweliadau gan y darparwr cofrestredig â sefydliadau
29. Sefyllfa ariannol

#### Pennod 4

- Hysbysiadau sydd i'w rhoi i'r awdurdod cofrestru
30. Hysbysu am farwolaeth neu absenoldeb diawdurdod claf a gedwir yn gaeth neu sy'n agored i'w gaethiwo o dan Ddeddf Iechyd Meddwl 1983
  31. Hysbysu ddiwyddiadau
  32. Hysbysu ynghylch absenoldeb person cofrestredig
  33. Hysbysu ynghylch newidiadau
  34. Penodi datodwyr etc
  35. Marwolaeth person cofrestredig

#### RHAN IV – GOFYNION YCHWANEGOL SY'N GYMWYS I YSBYTAI ANNIBYNNOL

#### Pennod 1

##### Gwasanaethau patholeg, dadebru a thrin plant mewn ysbytai annibynnol

36. Cymhwyso rheoliadau 37 i 39
37. Gwasanaethau patholeg
38. Dadebru
39. Trin plant

16. Safeguarding patients from abuse
17. Capacity of patients
18. Privacy, dignity and relationships
19. Assessing and monitoring the quality of service provision including annual returns
20. Staffing
21. Fitness of workers
22. Guidance for health care professionals
23. Records
24. Complaints
25. Research

#### Chapter 2

##### Premises

26. Fitness of premises
27. Fitness of premises – learning disability

#### Chapter 3

##### Management

28. Visits by registered provider to establishments
29. Financial position

#### Chapter 4

##### Notices to be given to the registration authority

30. Notification of death or unauthorised absence of a patient who is detained or liable to be detained under the Mental Health Act 1983
31. Notification of events
32. Notice of absence of registered person
33. Notice of changes
34. Appointment of liquidators etc
35. Death of registered person

#### PART IV – ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT HOSPITALS

#### Chapter 1

##### Pathology services, resuscitation and treatment of children in independent hospitals

36. Application of regulations 37 to 39
37. Pathology services
38. Resuscitation
39. Treatment of children

## Pennod 2

Ysbytai annibynnol lle y darperir gwasanaethau rhestredig penodol

40. Gweithdrefnau llawfeddygol
41. Triniaeth ddeintyddol o dan anaesthesia cyffredinol
42. Gwasanaethau obstetrig – staffio
43. Gwasanaethau obstetrig – gofynion pellach
44. Terfynu beichiogrwydd
45. Defnyddio technegau neu dechnolegau penodol

## Pennod 3

Ysbytai Iechyd Meddwl

46. Cymhwyso rheoliadau 47 i 50
47. Diogelwch cleifion ac eraill
48. Ymwelwyr
49. Cofnodion iechyd meddwl

RHAN V – GOFYNION YCHWANEGOL SY'N GYMWYS I GLINIGAU ANNIBYNNOL

50. Clinigau annibynnol

RHAN VI – AMRYWIOL

51. Cydymffurfio â rheoliadau
52. Tramgwyddau
53. Darpariaethau trosiannol
54. Dirymu ac arbedion

YR ATODLENNI

1. Gwybodaeth sydd i'w chynnwys yn y datganiad o ddiben
2. Yr wybodaeth sy'n ofynnol ynglŷn â phersonau sy'n bwriadu rhedeg, rheoli neu weithio mewn sefydliad neu asiantaeth
3. Rhan I – Y cyfnod y mae'n rhaid dal gafael ar gofnodion meddygol  
Rhan II – Cofnodion sydd i'w cynnal ar gyfer arolygu
4. Rhan I – Y manylion sydd i'w cofnodi mewn perthynas â chleifion sy'n cael gwasanaethau obstetrig  
Rhan II – Y manylion sydd i'w cofnodi mewn perthynas â phlentyn a enir mewn ysbyty annibynnol

## Chapter 2

Independent hospitals in which certain listed services are provided

40. Surgical procedures
41. Dental treatment under general anaesthetic
42. Obstetric services staffing
43. Obstetric services further requirements
44. Termination of pregnancies
45. Use of certain techniques or technology

## Chapter 3

Mental health hospitals

46. Application of regulations 47 to 50
47. Safety of patients and others
48. Visitors
49. Mental health records

PART V – ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT CLINICS

50. Independent clinics

PART VI – MISCELLANEOUS

51. Compliance with regulations
52. Offences
53. Transitional provisions
54. Revocation and savings

SCHEDULES

1. Information to be included in the statement of purpose
2. Information required in respect of persons seeking to carry on, manage or work at an establishment or agency
3. Part I – Period for which medical records must be retained  
Part II – Records to be maintained for inspection
4. Part I – Details to be recorded in respect of patients receiving obstetric services  
Part II – Details to be recorded in respect of a child born in an independent hospital

Mae Gweinidogion Cymru(1), gan arfer y pwerau a roddwyd iddynt gan adrannau 2(4), (7)(f) ac (8), 22(1), (2)(a) i (d), (f) i (j), (5)(a) a (7)(a) i (h), (j) a (k), 25(1), 33, 34(1), 35 a 118(5) i (7) o Ddeddf Safonau Gofal 2000(2) ac ar ôl ymgynghori â'r cyfryw bersonau a ystyriant yn briodol(3), drwy hyn yn gwneud y Rheoliadau canlynol.

## RHAN 1

### Cyffredinol

#### Enwi, cychwyn a chymhwyso

1.–(1) Enw'r Rheoliadau hyn yw Rheoliadau Gofal Iechyd Annibynnol (Cymru) 2011 a deuant i rym ar 5 Ebrill 2011.

(2) Mae'r Rheoliadau hyn yn gymwys o ran Cymru yn unig.

#### Dehongli

2.–(1) Yn y Rheoliadau hyn, oni fydd y cyd-destun yn mynnu fel arall–

ystyr "arweiniad y cleifion" ("*patients' guide*") yw'r arweiniad a lunnir yn unol â rheoliad 7;

ystyr "asiantaeth" ("*agency*") yw asiantaeth feddygol annibynnol;

ystyr "Awdurdod Gwasanaethau Ariannol" ("*Financial Services Authority*") yw'r corff a sefydlwyd o dan adran 1 o Ddeddf Gwasanaethau a Marchnadoedd Ariannol 2000(4);

mae "breintiau ymarfer" ("*practising privileges*"), mewn perthynas ag ymarferydd meddygol, yn cyfeirio at roi hawl i berson nas cyflogir mewn ysbyty annibynnol i ymarfer yn yr ysbyty hwnnw;

ystyr "bydwraig" ("*midwife*") yw bydwraig gofrestredig sydd wedi hysbysu'r awdurdod goruchwyliol lleol o'i bwriad i ymarfer yn unol ag unrhyw reolau a wnaed o dan erthygl 42 o Orchymyn Nyrso a Bydwreigiaeth 2001(5);

(1) Yr awdurdod cofrestru mewn perthynas â Chymru yw Cynulliad Cenedlaethol Cymru (*gweler* adran 5(1)(b) o Ddeddf Safonau Gofal 2000). Trosglwyddwyd y pwerau hyn i Weinidogion Cymru gan baragraff 30 o Atodlen 11 i Ddeddf Llywodraeth Cymru 2006 (p.32).

(2) 2000 p.14.

(3) *Gweler* adran 22(9) o Ddeddf Safonau Gofal 2000 ynglŷn â'r gofyniad i ymgynghori.

(4) 2000 p.8.

(5) O.S. 2002/253.

The Welsh Ministers(1), in exercise of powers conferred on them by sections 2(4), (7)(f) and (8), 22(1),(2)(a) to (d), (f) to (j), (5)(a) and (7)(a) to (h), (j) and (k), 25(1), 33, 34(1), 35 and 118(5) to (7) of the Care Standards Act 2000(2) and having consulted such persons as they considers appropriate(3), hereby make the following Regulations.

## PART 1

### General

#### Title, commencement and application

1.–(1) The title of these Regulations is the Independent Health Care (Wales) Regulations 2011 and they come into force on 5 April 2011.

(2) These Regulations apply in relation to Wales only.

#### Interpretation

2.–(1) In these Regulations, unless the context otherwise requires–

"the 2005 Act" ("*Deddf 2005*") means the Mental Capacity Act 2005(4);

"the Act" ("*y Ddeddf*") means the Care Standards Act 2000;

"agency" ("*asiantaeth*") means an independent medical agency;

"appropriate office of the registration authority" ("*swyddfa briodol yr awdurdod cofrestru*") means in relation to an establishment or agency–

(a) if an office has been specified under paragraph (2) for the area in which the establishment or agency is situated, that office;

(b) in any other case, any office of the registration authority;

"approved places" ("*lleoedd cymeradwy*") means, in relation to an independent hospital, a bed which is available in accordance with any condition

(1) The registration authority in relation to Wales is the National Assembly for Wales (*see* section 5(1)(b) of the Care Standards Act 2000). These powers are transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32).

(2) 2000 c.14.

(3) *See* section 22(9) of the Care Standards Act 2000 for the requirement to consult.

(4) 2005 c.9.

ystyr "claf" ("*patient*"), mewn perthynas â sefydliad neu asiantaeth, yw person y mae triniaeth yn cael ei darparu iddo yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth;

ystyr "cofnod gofal iechyd" ("*health care record*") yw unrhyw gofnod—

- (a) a gyfansoddir o wybodaeth am iechyd neu gyflwr corfforol neu feddyliol unigolyn, a
- (b) sydd wedi ei wneud gan neu ar ran proffesiynolyn iechyd mewn cysylltiad â gofal yr unigolyn hwnnw;

ystyr "cofrestr feddygol arbenigol" ("*specialist medical register*") yw'r gofrestr o ymarferwyr meddygol arbenigol a gedwir gan y Cyngor Meddygol Cyffredinol yn unol ag adran 34(D) o Ddeddf Meddygaeth 1983(1);

ystyr "corff" ("*organisation*") yw corff corfforaethol;

ystyr "darparwr cofrestredig" ("*registered provider*"), mewn perthynas â sefydliad neu asiantaeth, yw person sydd wedi'i gofrestru o dan Ran II o'r Ddeddf fel y person sy'n rhedeg y sefydliad neu'r asiantaeth;

ystyr "darparwr yswiriant" ("*insurance provider*") yw—

- (a) person a reoleiddir gan yr Awdurdod Gwasanaethau Ariannol ac sy'n gwerthu yswiriant neu sy'n tanysgrifennu risg yswiriant o'r fath, neu
- (b) asiant person o'r fath;

ystyr "datganiad o ddiben" ("*statement of purpose*") yw'r datganiad ysgrifenedig a lunnir yn unol â rheoliad 6;

ystyr "Deddf 2005" ("*the 2005 Act*") yw Deddf Galluedd Meddyliol 2005(2);

ystyr "Deddf y GIG" ("*the NHS Act*") yw Deddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(3);

ystyr "deintydd" ("*dentist*") yw person sydd wedi'i gofrestru yn y gofrestr ddeintyddion o dan Ddeddf Deintyddion 1984(4);

mae i "dyfais feddygol" yr ystyr a roddir i "*medical device*" yn Rheoliadau Dyfeisiau Meddygol 2002(5);

ystyr "y Ddeddf" ("*the Act*") yw Deddf Safonau Gofal 2000;

placed upon the registration of any person in respect of the independent hospital, for the use by a patient at night;

"dentist" ("*deintydd*") means a person registered in the dentists register under the Dentists Act 1984(1);

"establishment" ("*sefydliad*") means an independent hospital or an independent clinic;

"Financial Services Authority" ("*Awdurdod Gwasanaethau Ariannol*") means the body established under section 1 of the Financial Services and Markets Act 2000(2);

"general practitioner" ("*ymarferydd cyffredinol*") means a medical practitioner who provides primary medical services pursuant to sections 41, 42 and 50 of the NHS Act;

"health care professional" ("*proffesiynolyn gofal iechyd*") means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999(3) applies and "health care profession" must be construed accordingly;

"health care record" ("*cofnod gofal iechyd*") means any record which—

- (a) consists of information relating to the physical or mental health or condition of an individual, and
- (b) has been made by or on behalf of a health professional in connection with the care of that individual;

"insurance provider" ("*darparwr yswiriant*") means—

- (a) a person regulated by the Financial Services Authority who sells insurance, or underwrites the risk of such insurance, or
- (b) the agent of such a person;

"medical device" ("*dyfais feddygol*") has the same meaning as in the Medical Devices Regulations 2002(4);

"medical practitioner" ("*ymarferydd meddygol*") means a registered medical practitioner;

"midwife" ("*bydwraig*") means a registered midwife who has notified her intention to practise to the local supervisory authority in accordance with any rules made under article 42 of the Nursing and Midwifery Order 2001(5);

"the NHS Act" ("*Deddf y GIG*") means the National Health Service (Wales) Act 2006(6);

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(1) 1983 p.54. Mewnysodwyd yr adran hon gan O.S.2010/234 (erthygl 4, Atodlen 1, paragraff 10).

(2) 2005 p.9.

(3) 2006 p.42.

(4) 1984 p.24.

(5) O.S. 2002/618.

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(1) 1984 c.24.

(2) 2000 c.8.

(3) 1999 c.8.

(4) S.I. 2002/618.

(5) S.I. 2002/253.

(6) 2006 c.42.



ystyr "lleoedd cymeradwy" ("*approved places*"), mewn cysylltiad ag ysbyty annibynnol, yw gwelyau sydd ar gael yn unol ag unrhyw amod a osodwyd ar gofrestrriad unrhyw berson mewn perthynas â'r ysbyty annibynnol, i'w ddefnyddio gan glaf yn ystod y nos;

ystyr "person cofrestredig" ("*registered person*"), mewn perthynas â sefydliad neu asiantaeth, yw unrhyw berson sy'n ddarparwr cofrestredig neu'n rheolwr cofrestredig y sefydliad neu'r asiantaeth;

ystyr "proffesiynolyn gofal iechyd" ("*health care professional*") yw person sydd wedi'i gofrestru fel aelod o unrhyw broffesiwn y mae adran 60(2) o Ddeddf Iechyd 1999(1) yn gymwys iddo, a rhaid dehongli "proffesiwn gofal iechyd" yn unol â hynny;

ystyr "rheolwr cofrestredig" ("*registered manager*"), mewn perthynas â sefydliad neu asiantaeth, yw person sydd wedi'i gofrestru o dan Ran II o'r Ddeddf fel rheolwr y sefydliad neu'r asiantaeth;

ystyr "sefydliad" ("*establishment*") yw ysbyty annibynnol neu glinig annibynnol;

ystyr "swyddfa briodol yr awdurdod cofrestru" ("*appropriate office of the registration authority*") mewn perthynas â sefydliad neu asiantaeth yw—

- (a) os pennwyd swyddfa o dan baragraff (2) ar gyfer yr ardal y lleolir y sefydliad neu asiantaeth ynddi, y swyddfa honno;
- (b) mewn unrhyw achos arall, unrhyw swyddfa'r awdurdod cofrestru;

mae "triniaeth" ("*treatment*") yn cynnwys gofal lliniarol, gwasanaethau nyrsio a gwasanaethau rhestredig o fewn yr ystyr a roddir i "listed services" yn adran 2 o'r Ddeddf;

mae "unigolyn cyfrifol" ("*responsible individual*") i'w dehongli yn unol â rheoliad 10;

ystyr "ymarferydd cyffredinol" ("*general practitioner*") yw ymarferydd meddygol sy'n darparu gwasanaethau meddygol sylfaenol yn unol ag adrannau 41, 42 a 50 o Ddeddf y GIG;

ystyr "ymarferydd meddygol" ("*medical practitioner*") yw ymarferydd meddygol cofrestredig.

(2) Caiff yr awdurdod cofrestru bennu swyddfa a reolir ganddo fel y swyddfa briodol mewn perthynas â sefydliadau ac asiantaethau a leolir mewn rhan benodol o Gymru.

(3) Yn y Rheoliadau hyn, mae cyfeiriad—

"organisation" ("*corff*") means a body corporate;

"patient" ("*claf*"), in relation to an establishment or agency, means a person for whom treatment is provided in or for the purposes of the establishment or for the purposes of the agency;

"patients' guide" ("*arweiniad y cleifion*") means the guide compiled in accordance with regulation 7;

"practising privileges" ("*breintiau ymarfer*"), in relation to a medical practitioner, refers to the grant to a person who is not employed in an independent hospital of permission to practise in that hospital;

"registered manager" ("*rheolwr cofrestredig*"), in relation to an establishment or agency, means a person who is registered under Part II of the Act as the manager of the establishment or agency;

"registered person" ("*person cofrestredig*"), in relation to an establishment or agency, means any person who is the registered provider or the registered manager of the establishment or agency;

"registered provider" ("*darparwr cofrestredig*"), in relation to an establishment or agency, means a person who is registered under Part II of the Act as the person carrying on the establishment or agency;

"responsible individual" ("*unigolyn cyfrifol*") is to be construed in accordance with regulation 10;

"specialist medical register" ("*cofrestr feddygol arbenigol*") means the register of specialist medical practitioners kept by the General Medical Council in accordance with section 34D of the Medical Act 1983(1);

"statement of purpose" ("*datganiad o ddiben*") means the written statement compiled in accordance with regulation 6;

"treatment" ("*triniaeth*") includes palliative care, nursing and listed services, within the meaning of section 2 of the Act.

(2) The registration authority may specify an office controlled by it as the appropriate office in relation to establishments and agencies situated in a particular area of Wales.

(3) In these Regulations, a reference—

(1) 1999 p.8.

(1) 1983 c.54. This section was inserted by S.I.2010/234 (article 4, Schedule 1, paragraph 10).

- (a) at reoliad neu Atodlen â rhif yn gyfeiriad at y rheoliad yn y Rheoliadau hyn sy'n dwyn y rhif hwnnw, neu at yr Atodlen iddynt sy'n dwyn y rhif hwnnw;
- (b) mewn rheoliad neu Atodlen at baragraff â rhif yn gyfeiriad at y paragraff yn y rheoliad hwnnw neu'r Atodlen honno sy'n dwyn y rhif hwnnw;
- (c) mewn paragraff at is-baragraff â llythyren neu rif yn gyfeiriad at yr is-baragraff yn y paragraff hwnnw sy'n dwyn y llythyren honno neu'r rhif hwnnw.

(4) Yn y Rheoliadau hyn, onid yw'n ymddangos bod bwriad i'r gwrthwyneb, mae cyfeiriadau at gyflogi person yn cynnwys cyflogi person pa un ai o dan gontract gwasanaeth neu gontract am wasanaethau a rhaid dehongli cyfeiriadau at gyflogai neu at berson a gyflogir yn unol â hynny.

### Ystyr "ysbyty annibynnol"

3.–(1) Yn ddarostyngedig i baragraff (2), mae triniaeth gan ddefnyddio unrhyw un o'r technegau neu'r technolegau canlynol yn rhagnodedig ("*prescribed*") at ddibenion adran 2(7)(f) o'r Ddeddf–

- (a) cynnyrch laser Dosbarth 3B neu Ddosbarth 4, fel y'i diffinnir yn Rhan 1 o Safon Brydeinig EN 60825-1 (Diogelwch ymbelydredd cynhyrchion a systemau laser)(1);
- (b) golau dwys, sef golau anghydlynol band eang a hidlir i gynhyrchu amrediad penodedig o donfeddi, pan ddefnyddir y pelydriad hidledig hwnnw ar y corff gyda'r nod o beri difrod thermol, mecanyddol neu gemegol i ffoliglau blew a meflau ar y croen, tra'n arbed y meinweoedd o amgylch;
- (c) enwaedu plant gwrywaidd gan broffesiynolyn gofal iechyd, gan gynnwys gwneud hynny at ddibenion defod grefyddol;
- (ch) hemodialysis neu ddialysis peritoneol;
- (d) endosgopi;
- (dd) therapi hyperbarig, sef gweini ocsigen (pa un ai ar y cyd ag un neu ragor o nwyon eraill ai peidio) i glaf mewn siambr seliedig a wasgeddir yn raddol ag aer cywasgedig, pan gyflawnir y cyfryw therapi gan neu o dan oruchwyliaeth neu gyfarwyddyd uniongyrchol ymarferydd meddygol ac y defnyddir y siambr honno fel arall yn bennaf ar gyfer trin gweithwyr mewn cysylltiad â'r gwaith a gyflawnant; ac
- (e) technegau ffrwythloni *in vitro*, sef gwasanaethau triniaeth y gellir rhoi trwydded

- (a) to a numbered regulation or Schedule is to the regulation in, or Schedule to, these Regulations bearing that number;
- (b) in a regulation or Schedule to a numbered paragraph, is to the paragraph in that regulation or Schedule bearing that number;
- (c) in a paragraph to a lettered or numbered sub-paragraph is to the sub-paragraph in that paragraph bearing that letter or number.

(4) In these Regulations, unless the contrary intention appears, references to employing a person include employing a person whether under a contract of service or a contract for services and references to an employee or to a person being employed is to be construed accordingly.

### Meaning of "independent hospital"

3.–(1) Subject to paragraph (2), for the purposes of section 2(7)(f) of the Act, treatment using any of the following techniques or technology are prescribed–

- (a) a Class 3B or Class 4 laser product, as defined in Part I of British Standard EN 60825-1 (Radiation safety of laser products and systems)(1);
- (b) an intense light, being broadband non-coherent light which is filtered to produce a specified range of wavelengths, such filtered radiation being delivered to the body, with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues;
- (c) circumcision of male children by a health care professional, including for the purpose of religious observance;
- (d) haemodialysis or peritoneal dialysis;
- (e) endoscopy;
- (f) hyperbaric therapy, being the administration of oxygen (whether or not combined with one or more other gases) to a patient who is in a sealed chamber which is gradually pressurised with compressed air, where such therapy is carried out by or under the direct supervision or direction of a medical practitioner and where the primary use of that chamber is otherwise than for the treatment of workers in connection with the work which they perform; and
- (g) *in vitro* fertilisation techniques, being treatment services for which a licence may be

(1) Gellir cael copïau o BS EN 60825-1 gan BSI Customer Services, 389 Chiswick High Road, London W4 4AL.

(1) Copies of BS EN 60825-1 may be obtained from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.

ar eu cyfer o dan baragraff 1 o Atodlen 2 i Ddeddf Ffrwythloni ac Embryoleg Dynol 1990(1).

(2) Nid yw "gwasanaethau rhestredig" yn cynnwys triniaeth drwy ddefnyddio'r technegau neu'r technolegau canlynol—

- (a) triniaeth i leddfu poen yn y cyhyrau a'r cymalau drwy ddefnyddio lamp triniaeth gwres is-goch;
- (b) triniaeth drwy ddefnyddio cynnyrch laser Dosbarth 3B, pan fo'r driniaeth honno yn cael ei chyflawni gan broffesiynolyn gofal iechyd neu o dan oruchwyliaeth proffesiynolyn gofal iechyd;
- (c) defnyddio cyfarpar (nad yw'n gyfarpar sy'n dod o dan baragraff (1)(b)) i gael lliw haul artiffisial, sef cyfarpar a gyfansoddir o lamp neu lampau sy'n allyrru pelydrau uwchfioled.

(3) At ddibenion adran 2 o'r Ddeddf, mae sefydliadau o'r disgrifiadau canlynol wedi'u heithrio rhag bod yn ysbytai annibynnol—

- (a) sefydliad sy'n ysbyty yn rhinwedd adran 2(3)(a)(i) oherwydd, yn unig, mai darparu triniaeth feddygol neu seiciatrïg ar gyfer afiechyd neu anhwylder meddwl neu ofal lliniarol yw ei brif ddiben, ond nad oes ganddo leoedd cymeradwy;
- (b) sefydliad sy'n ysbyty i'r lluoedd arfog o fewn yr ystyr a roddir i "service hospital" yn Atodlen 12 o Ddeddf Lluoedd Arfog 2006(2);
- (c) sefydliad sydd yn, neu sy'n ffurfio rhan o, garchar, canolfan remand, sefydliad troseddwyr ifanc neu ganolfan hyfforddi ddiogel o fewn yr ystyron a roddir, yn eu trefn i "prison", "remand centre", "young offender institution" neu "secure training centre" yn Neddf Carchardai 1952(3);
- (ch) sefydliad (nad yw'n ysbyty'r gwasanaeth iechyd) sydd â'r unig neu'r prif ddiben o ddarparu gwasanaethau meddygol gan ymarferydd neu ymarferwyr cyffredinol o fewn ystyr Rhan IV o Ddeddf y GIG; ac ni fydd sefydliad o'r fath yn ysbyty annibynnol o ganlyniad i ddarparu gwasanaethau rhestredig i glaf neu gleifion gan y cyfryw ymarferydd neu ymarferwyr cyffredinol;
- (d) preswylfa breifat claf neu gleifion lle y darperir triniaeth i'r cyfryw glaf neu gleifion, ond nid i neb arall;
- (dd) meysydd chwarae a champfeydd lle mae proffesiynolion gofal iechyd yn darparu triniaeth i bersonau sy'n cymryd rhan mewn gweithgareddau a digwyddiadau chwaraeon; ac

granted under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990(1).

(2) "Listed services" do not include treatment using the following techniques or technology—

- (a) treatment for the relief of muscular and joint pain using an infra-red heat treatment lamp;
- (b) treatment using a Class 3B laser product where such treatment is carried out by or under the supervision of a health care professional;
- (c) the use of an apparatus (not being an apparatus falling within paragraph (1)(b)) for acquiring an artificial suntan, consisting of a lamp or lamps emitting ultraviolet rays.

(3) For the purposes of section 2 of the Act, establishments of the following descriptions are excepted from being independent hospitals—

- (a) an establishment which is a hospital by virtue of section 2(3)(a)(i) solely because its main purpose is to provide medical or psychiatric treatment for illness or mental disorder or palliative care but which has no approved places;
- (b) an establishment which is a service hospital within the meaning of Schedule 12 of the Armed Forces Act 2006(2);
- (c) an establishment which is, or forms part of, a prison, remand centre, young offender institution or secure training centre within the meaning of the Prison Act 1952(3);
- (d) an establishment (not being a health service hospital) which has as its sole or main purpose the provision by a general practitioner or practitioners of medical services within the meaning of Part IV of the NHS Act; and such an establishment will not be an independent hospital as the result of the provision of listed services to a patient or patients by such a general practitioner or practitioners;
- (e) the private residence of a patient or patients in which treatment is provided to such patient or patients but to no-one else;
- (f) sports grounds and gymnasia where health care professionals provide treatment to persons taking part in sporting activities and events; and

(1) 1990 p.37.

(2) 2006 p.52. *Gweler* paragraff 12 o'r Atodlen.

(3) 1952 p.52.

(1) 1990 c.37.

(2) 2006 c.52. *See* paragraph 12 of the Schedule.

(3) 1952 c.52.

- (e) meddygfa neu ystafell ymgynghori, (nad yw'n rhan o ysbyty), lle mae ymarferydd meddygol yn darparu gwasanaethau meddygol o dan drefniadau, yn unig, a wnaed ar ran y cleifion gan—
- (i) eu cyflogwr,
  - (ii) carchar neu sefydliad arall lle y cedwir y cleifion o dan glo, ac eithrio yn unol ag unrhyw ddarpariaeth o Ddeddf Iechyd Meddwl 1983(1), neu
  - (iii) darparwr yswiriant y mae'r cleifion yn ddeiliaid polisi yswiriant gydag ef, ac eithrio polisi yswiriant at yr unig ddiben, neu'r prif ddiben, o ddarparu buddion mewn perthynas â diagnosis neu driniaeth ar gyfer salwch, anabledd neu eiddilwch corfforol neu feddyliol;
- (f) sefydliad sy'n ysbyty yn rhinwedd adran 2(7)(a) o'r Ddeddf oherwydd, yn unig, ei fod yn darparu—
- (i) llawdriniaeth yr ewinedd,
  - (ii) gweithdrefnau gwely'r ewin, neu
  - (iii) ciwretio, serio neu rew-serio dafadennau, ferwcau neu friwiau eraill y croen,

ar unrhyw rannau o'r troed, ac yn defnyddio anesthesia lleol yn ystod y gweithdrefnau hynny; ac

- (ff) sefydliad sy'n ysbyty yn rhinwedd adran 2(7)(a) o'r Ddeddf oherwydd, yn unig, bod ymarferydd meddygol yn darparu ciwretio, serio neu rew-serio dafadennau, ferwcau neu friwiau eraill y croen ac yn defnyddio anesthesia lleol yn ystod y weithdrefn honno.

(4) Yn y rheoliad hwn, ystyr "anesthesia lleol" ("*local anaesthesia*") yw unrhyw anesthesia ac eithrio anesthesia cyffredinol, sbinol neu epidwrol, ac nid yw'n cynnwys rhoi ataliad nerf parthol.

(5) Mae'r diffiniad o "listed services" yn is-adran (7) o adran 2 o'r Ddeddf yn cael effaith fel petai'r geiriau "intravenously administered" wedi eu mewnosod ar ôl y gair "or" ym mharagraff (a) o'r diffiniad hwnnw.

### Ystyr "clinig annibynnol"

4.—(1) At ddibenion y Ddeddf, rhagnodir mai meddygfa neu ystafell ymgynghori lle y mae ymarferydd meddygol, nad yw'n darparu unrhyw wasanaethau yn unol â Ddeddf y GIG yn y sefydliad hwnnw, yn darparu gwasanaethau meddygol o unrhyw fath (gan gynnwys triniaeth seiciatrïg) ac eithrio o dan drefniadau a wnaed ar ran y cleifion gan eu cyflogwr yw clinig annibynnol

(2) Nid yw paragraff (1) yn gymwys os darperir y gwasanaethau meddygol o dan drefniadau, yn unig, a wnaed ar ran y cleifion gan—

- (g) a surgery or consulting room, (which is not part of a hospital), in which a medical practitioner provides medical services only under arrangements made on behalf of the patients by—
- (i) their employer,
  - (ii) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983(1), or
  - (iii) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity;
- (h) an establishment which is a hospital by virtue of section 2(7)(a) of the Act solely because it provides—
- (i) nail surgery,
  - (ii) nail bed procedures, or
  - (iii) curettage, cautery or the cryocautery of warts, verrucae or other skin lesions,

on any areas of the foot and uses local anaesthesia during these procedures; and

- (i) an establishment which is a hospital by virtue of section 2(7)(a) of the Act solely because a medical practitioner provides curettage, cautery or the cryocautery of warts, verrucae or other skin lesions and uses local anaesthesia during that procedure.

(4) In this regulation "local anaesthesia" ("*anesthesia lleol*") means any anaesthesia other than general, spinal or epidural anaesthesia, and also excludes the administration of a regional nerve block.

(5) The definition of "listed services" in subsection (7) of section 2 of the Act has effect as if in paragraph (a) of that definition the words "intravenously administered" were inserted after "or".

### Meaning of "independent clinic"

4.—(1) For the purposes of the Act a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the NHS Act in that establishment provides medical services of any kind (including psychiatric treatment) otherwise than under arrangements made on behalf of the patients by their employer, is prescribed as an independent clinic.

(2) Paragraph (1) does not apply if the medical services are provided only under arrangements made on behalf of the patients by—

(1) 1983 p.20.

(1) 1983 c.20.

- (i) carchar neu sefydliad arall lle y cedwir y cleifion o dan glo, ac eithrio yn unol ag unrhyw ddarpariaeth o Ddeddf Iechyd Meddwl 1983, neu
- (ii) darparwr yswiriant y mae'r cleifion yn ddeiliaid polisi yswiriant gydag ef, ac eithrio polisi yswiriant at yr unig ddiben, neu'r prif ddiben, o ddarparu buddion mewn perthynas â diagnosis neu driniaeth ar gyfer salwch, anabledd neu eiddilwch corfforol neu feddyliol.

(3) Pan fo dau neu fwy o ymarferwyr meddygol, yn defnyddio gwahanol rannau o'r un fangre fel meddygfa neu ystafell ymgynghori, neu'n defnyddio'r un feddygfa neu ystafell ymgynghori ar adegau gwahanol, ystyrir bod pob un o'r ymarferwyr meddygol yn cynnal clinig annibynnol ar wahân, onid ydynt yn yr un practis gyda'i gilydd.

### **Eithrio ymgymeriad o'r diffiniad o asiantaeth feddygol annibynnol**

5. At ddibenion y Ddeddf, rhaid eithrio unrhyw ymgymeriad a gyfansoddir, yn unig, o ddarparu gwasanaethau meddygol gan ymarferydd meddygol o dan drefniadau a wnaed ar ran y cleifion gan—

- (a) eu cyflogwr;
- (b) carchar neu sefydliad arall lle y cedwir y cleifion o dan glo, ac eithrio yn unol ag unrhyw ddarpariaeth o Ddeddf Iechyd Meddwl 1983; neu
- (c) darparwr yswiriant y mae'r cleifion yn ddeiliaid polisi yswiriant gydag ef, ac eithrio polisi yswiriant at yr unig ddiben, neu'r prif ddiben, o ddarparu buddion mewn perthynas â diagnosis neu driniaeth ar gyfer salwch, anabledd neu eiddilwch corfforol neu feddyliol,

rhag bod yn asiantaeth.

### **Datganiad o ddiben**

6.—(1) Rhaid i'r person cofrestredig lunio, mewn perthynas â'r sefydliad neu'r asiantaeth, ddatganiad ar bapur (sef datganiad y cyfeirir ato yn y Rheoliadau hyn fel "y datganiad o ddiben") y mae'n rhaid iddo gynnwys datganiad ynghylch y materion a restrir yn Atodlen 1.

(2) Rhaid i'r person cofrestredig ddarparu copi o'r datganiad o ddiben i swyddfa briodol yr awdurdod cofrestru a rhaid iddo drefnu bod copi o'r datganiad o ddiben ar gael i'w archwilio ar bob adeg resymol gan bob claf a chan unrhyw berson sy'n gweithredu ar ran claf.

(3) Yn ddarostyngedig i baragraff (4) rhaid i'r person cofrestredig sicrhau bod y sefydliad yn cael ei redeg, neu'r asiantaeth yn cael ei rhedeg, mewn modd sy'n

- (i) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983, or
- (ii) an insurance provider with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis of treatment of physical or mental illness, disability or infirmity.

(3) Where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical practitioners will be regarded as carrying on a separate independent clinic unless they are in practice together.

### **Exception of undertaking from the definition of independent medical agency**

5. For the purposes of the Act, any undertaking which consists of the provision of medical services by a medical practitioner only under arrangements made on behalf of the patients by—

- (a) their employer;
- (b) a prison or other establishment in which the patients are held in custody, other than pursuant to any provision of the Mental Health Act 1983; or
- (c) an insurance company with whom the patients hold an insurance policy, other than an insurance policy which is solely or primarily intended to provide benefits in connection with the diagnosis or treatment of physical or mental illness, disability or infirmity,

is excepted from being an agency.

### **Statement of purpose**

6.—(1) The registered person must compile in relation to the establishment or agency a statement on paper (in these Regulations referred to as "the statement of purpose") which must consist of a statement as to the matters listed in Schedule 1.

(2) The registered person must provide a copy of the statement of purpose to the appropriate office of the registration authority and must make a copy of it available upon request for inspection at any reasonable time by every patient and any person acting on behalf of a patient.

(3) Subject to paragraph (4) the registered person must ensure that the establishment or agency is conducted in a manner which is consistent with its

gyson â datganiad o ddiben y sefydliad neu'r asiantaeth.

(4) Ni oes dim sydd ym mharagraff (3), rheoliad 15(1) na reoliad 26(1) a (2) sy'n ei gwneud yn ofynnol nac yn awdurdodi bod y person cofrestredig yn torri neu'n peidio â chydymffurfio ag—

- (a) unrhyw ddarpariaeth arall o'r Rheoliadau hyn; neu
- (b) yr amodau sydd mewn grym ar y pryd mewn perthynas â chofrestru'r person cofrestredig o dan Ran II o'r Ddeddf.

### Arweiniad y cleifion

7.—(1) Rhaid i'r person cofrestredig baratoi arweiniad ysgrifenedig i'r sefydliad neu'r asiantaeth (y cyfeirir ato yn y Rheoliadau hyn fel "arweiniad y cleifion") ac mae'n rhaid i'r arweiniad gynnwys—

- (a) crynodeb o'r datganiad o ddiben;
- (b) yr amodau a'r telerau mewn perthynas â'r gwasanaethau sydd i'w darparu i'r cleifion, gan gynnwys yr amodau a'r telerau ynghylch y swm sydd i'w dalu gan gleifion am bob agwedd ar eu triniaeth a'r dull o dalu'r taliadau;
- (c) ffurf safonol o gontract ar gyfer darparu'r gwasanaethau a chyfleusterau gan y darparwr cofrestredig i gleifion;
- (ch) crynodeb o'r weithdrefn gwynion a sefydlwyd o dan reoliad 24;
- (d) pan fo ar gael, crynodeb o safbwyntiau'r cleifion ac eraill, a gafwyd yn unol â rheoliad 19(2)(d);
- (dd) cyfeiriad a rhif teleffon swyddfa briodol yr awdurdod cofrestru; ac
- (e) yr adroddiad arolygu diweddaraf a baratowyd gan yr awdurdod cofrestru neu wybodaeth ynglŷn â sut y gellir cael copi o'r adroddiad hwnnw.

(2) Rhaid i'r person cofrestredig ddarparu copi o arweiniad cyntaf y cleifion i swyddfa briodol yr awdurdod cofrestru, a rhaid iddo sicrhau bod copi o'r fersiwn gyfredol o arweiniad y cleifion yn cael ei ddarparu i bob claf ac i unrhyw berson sy'n gweithredu ar ran claf.

### Adolygu'r datganiad o ddiben ac arweiniad y cleifion

8. Rhaid i'r person cofrestredig—

- (a) cadw'r datganiad o ddiben a chynnwys arweiniad y cleifion dan arolwg, a phan fo'n briodol, eu diwygio; a
- (b) hysbysu swyddfa briodol yr awdurdod cofrestru ynghylch unrhyw ddiwygiad o'r fath, o leiaf 28 diwrnod cyn y bwriedir i'r diwygiad ddod i rym.

statement of purpose.

(4) Nothing in paragraph (3), regulation 15(1) or 26(1) and (2) requires or authorises the registered person to contravene, or not comply with—

- (a) any other provision of these Regulations; or
- (b) the conditions for the time being in force in relation to the registration of the registered person under Part II of the Act.

### Patients' guide

7.—(1) The registered person must produce a written guide to the establishment or agency (in these Regulations referred to as "the patients' guide") which must include—

- (a) a summary of the statement of purpose;
- (b) the terms and conditions in respect of services to be provided for patients, including as to the amount and method of payment of charges by patients for all aspects of their treatment;
- (c) a standard form of contract for the provision of services and facilities by the registered provider to patients;
- (d) a summary of the complaints procedure established under regulation 24;
- (e) where available, a summary of the views of patients and others obtained in accordance with regulation 19(2)(e);
- (f) the address and telephone number of the appropriate office of the registration authority; and
- (g) the most recent inspection report prepared by the registration authority or information as to how a copy of that report may be obtained.

(2) The registered person must provide a copy of the first patients' guide to the appropriate office of the registration authority, and must ensure that a copy of the current version of the patient's guide is provided to every patient and any person acting on behalf of a patient.

### Review of statement of purpose and patients' guide

8. The registered person must—

- (a) keep under review and, where appropriate, revise the statement of purpose and the content of the patients' guide; and
- (b) notify the appropriate office of the registration authority of any such revision at least 28 days before it is to take effect.

## Polisiau a gweithdrefnau

9.–(1) Rhaid i'r person cofrestredig baratoi a rhoi ar waith ddatganiadau ysgrifenedig o'r polisiau sydd i'w defnyddio a'r gweithdrefnau sydd i'w dilyn mewn neu at ddibenion sefydliad mewn perthynas â phob un o'r materion a bennir isod, ac at ddibenion asiantaeth, mewn perthynas â phob un o'r materion a bennir yn is-baragraffau (b), (ch), (dd), (e), (f), (ff), (i) a (j)–

- (a) y trefniadau ar gyfer cymryd i mewn neu dderbyn cleifion, eu trosglwyddo i ysbyty, gan gynnwys i ysbyty gwasanaeth iechyd, pan fo angen ac, yn achos sefydliad sydd â lleoedd cymeradwy, eu rhyddhau;
- (b) y trefniadau ar gyfer asesu, gwneud diagnosis a thrin cleifion;
- (c) sicrhau bod mangre'r sefydliad bob amser yn addas at y diben y'i defnyddir ar ei chyfer;
- (ch) monitro ansawdd ac addasrwydd y cyfleusterau a'r cyfarpar, gan gynnwys cynnal y cyfryw gyfarpar;
- (d) adnabod, asesu a rheoli risgiau sy'n gysylltiedig â gweithredu'r sefydliad, i gyflogeion, cleifion, ymwelwyr a'r rhai sy'n gweithio yn, neu at ddibenion, y sefydliad;
- (dd) creu, rheoli, trin a storio cofnodion a gwybodaeth arall;
- (e) darparu gwybodaeth i gleifion ac eraill;
- (f) recriwtio, sefydlu a chadw cyflogeion, a'u hamodau gwaith;
- (ff) sicrhau bod staff yn cael eu recriwtio mewn ffordd ddiogel, gan gynnwys gwiriadau sy'n briodol i'r gwaith y mae'r staff i ymgymryd ag ef;
- (g) os cynhelir ymchwil mewn sefydliad, sicrhau y gwneir hynny gyda chydysyniad unrhyw glaf neu gleifion a gynhwysir yn yr ymchwil, bod yr ymchwil yn briodol ar gyfer y sefydliad dan sylw, ac y'i cynhelir yn unol â'r canllawiau cyhoeddedig cyfredol ac awdurdodol ar gynnal prosiectau ymchwil;
- (ng) y trefniadau ar gyfer sicrhau iechyd a diogelwch y staff a'r cleifion;
- (h) cadw eiddo a meddiannau cleifion yn ddiogel yn y sefydliad, mewn achosion pan gymerir y cyfryw eiddo neu feddiannau oddi ar y claf, oherwydd y gallant fod yn risg o niwed i'r claf;
- (i) archebu, cofnodi, gweini a chyflenwi meddyginiaethau i gleifion;
- (l) y trefniadau mewn perthynas â rheoli heintiau gan gynnwys hylendid dwylo, trin a gwaredu gwastraff clinigol yn ddiogel, trefniadau cadw tŷ a glanhau, a hyfforddiant a chyngor perthnasol;

## Policies and procedures

9.–(1) The registered person must prepare and implement written statements of the policies to be applied and the procedures to be followed in or for the purposes of an establishment in relation to each of the matters specified below and for the purposes of an agency each of the matters specified in sub-paragraphs (b), (d), (f), (g), (h), (i), (m) and (n)–

- (a) the arrangements for admission or acceptance of patients, their transfer to a hospital, including to a health service hospital, where required and, in the case of an establishment which has approved places, their discharge;
- (b) the arrangements for assessment, diagnosis and treatment of patients;
- (c) ensuring that the establishment premises are at all times fit for the purpose for which they are used;
- (d) monitoring the quality and suitability of facilities and equipment, including maintenance of such equipment;
- (e) identifying, assessing and managing risks associated with the operation of the establishment to employees, patients, visitors and those working in or for the purposes of the establishment;
- (f) the creation, management, handling and storage of records and other information;
- (g) the provision of information to patients and others;
- (h) the recruitment, induction and retention of employees and their employment conditions;
- (i) ensuring safe recruitment of staff including undertaking checks appropriate to the work that staff are to undertake;
- (j) ensuring that, where research is carried out in an establishment, it is carried out with the consent of any patient or patients involved, is appropriate for the establishment concerned and is conducted in accordance with up-to-date and authoritative published guidance on the conduct of research projects;
- (k) the arrangements for ensuring the health and safety of staff and patients;
- (l) the safe keeping of patient property and possessions in an establishment in cases where such property or possessions have been removed from the patient as they may put the patient at risk of harm;
- (m) the ordering, recording, administration and supply of medicines to patients;
- (n) the arrangements relating to infection control including hand hygiene, safe handling and disposal of clinical waste, housekeeping and cleaning regimes and relevant training and advice;

- (ll) y trefniadau ar gyfer cynnal archwiliadau clinigol; ac
- (m) rhoi breintiau ymarfer i ymarferwyr meddygol a'u tynnu'n ôl mewn sefydliadau lle y rhoddir neu y caniateir rhoi breintiau o'r fath.
- (2) Rhaid i'r person cofrestredig baratoi a gweithredu polisi ysgrifenedig sy'n pennu—
- (a) sut y rheolir ymddygiad claf sy'n ymddwyn yn gythryblus;
- (b) y mesurau atal a ganiateir, ac o dan ba amgylchiadau y caniateir eu defnyddio;
- (c) gofynion bod cyflogeion yn adrodd am achosion difrifol o drais neu hunan-niweidio, gan gynnwys canllawiau ar sut i gategoreiddio'r digwyddiadau hynny; ac
- (ch) y weithdrefn ar gyfer adolygu digwyddiadau o'r fath a phenderfynu ar y camau sydd i'w cymryd wedi hynny.
- (3) Rhaid paratoi'r datganiadau a'r polisïau ysgrifenedig y cyfeirir atynt ym mharagraffau (1) a (2) gan roi sylw i faint y sefydliad neu'r asiantaeth, y datganiad o ddiben a nifer ac anghenion y cleifion.
- (4) Rhaid i'r person cofrestredig baratoi a gweithredu datganiadau ysgrifenedig o'r polisïau sydd i'w defnyddio a'r gweithdrefnau sydd i'w dilyn, mewn neu at ddibenion sefydliad neu asiantaeth, a fydd yn sicrhau—
- (a) yr asesir galluedd pob claf i gydsynio i driniaeth;
- (b) yn achos claf sydd â galluedd, y sicrheir ei ganiatâd priodol a gwybodus, ac mewn ysgrifen pan fo'n briodol, i driniaeth cyn rhoi unrhyw driniaeth arfaethedig;
- (c) yn achos claf nad oes ganddo alluedd, y cydymffurfir â gofynion Deddf 2005 cyn rhoi unrhyw driniaeth arfaethedig iddo;
- (ch) y cymerir i ystyriaeth y canllawiau cenedlaethol a'r canllawiau arferion gorau; a
- (d) y datgelir gwybodaeth am iechyd a thriniaeth y claf i'r personau hynny, yn unig, sydd arnynt angen i fod yn ymwybodol o'r wybodaeth honno er mwyn trin y claf yn effeithiol neu leihau unrhyw risg y gallai'r claf niweidio ei hunan neu berson arall, neu at y diben o weinyddu'r sefydliad yn briodol.
- (5) Rhaid i'r person cofrestredig adolygu gweithrediad polisïau a gweithdrefnau a weithredir o dan—
- (a) y rheoliad hwn;
- (b) rheoliad 24; ac
- (c) i'r graddau y maent yn gymwys i'r person
- (o) the arrangements for clinical audit; and
- (p) the granting, and withdrawal, of practising privileges to medical practitioners in establishments where such privileges are or may be granted.
- (2) The registered person must prepare and implement a written policy setting out—
- (a) how disturbed behaviour exhibited by a patient is to be managed;
- (b) permitted measures of restraint and the circumstances in which they may be used;
- (c) requirements for employees to report serious incidents of violence or self harm, including guidance as to how those incidents should be classified; and
- (d) the procedure for review of such incidents and determination of the action which is to be taken subsequently.
- (3) The written statements and policies referred to in paragraphs (1) and (2) must be prepared having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients.
- (4) The registered person must prepare and implement written statements of policies to be applied and procedures to be followed in or for the purposes of an establishment or agency which ensure that—
- (a) the capacity of each patient to consent to treatment is assessed;
- (b) in the case of a patient who has capacity, properly informed, and where appropriate, written consent to treatment is obtained before any proposed treatment is administered;
- (c) in the case of a patient who lacks capacity the requirements of the 2005 Act are complied with before any treatment proposed for him is administered;
- (d) national and best practice guidance is taken into account; and
- (e) information about a patient's health and treatment is disclosed only to those persons who need to be aware of that information in order to treat the patient effectively or minimise any risk of the patient harming himself or herself or another person, or for the purpose of the proper administration of the establishment.
- (5) The registered person must review the operation of policies and procedures implemented under—
- (a) this regulation;
- (b) regulation 24; and
- (c) in so far as they apply to the registered person,



cofrestredig, rheoliadau 38, 44 (7) a 48;

a hynny fesul cyfnodau o ddim mwy na thair blynedd a rhaid iddo, pan fo'n briodol, adolygu a gweithredu'r polisiau a'r gweithdrefnau hynny.

(6) Rhaid i'r person cofrestredig gadw copïau o'r holl bolisiau a gweithdrefnau y cyfeirir atynt yn y rheoliad hwn, gan gynnwys fersiynau blaenorol o bolisiau a gweithdrefnau a adolygwyd yn unol â pharagraff (5), am gyfnod o ddim llai na thair blynedd o ddyddiad creu neu ddiwygio'r polisi neu weithdrefn.

(7) Rhaid i'r person cofrestredig sicrhau bod copi o'r holl ddatganiadau ysgrifenedig a baratoir yn unol â'r rheoliad hwn ar gael i'w harchwilio gan yr awdurdod cofrestru.

## RHAN II

### Personau Cofrestredig

#### Ffitrwydd y darparwr cofrestredig

**10.**–(1) Rhaid i berson beidio â rhedeg sefydliad neu asiantaeth onid yw'n berson ffit i wneud hynny.

(2) Nid yw person yn ffit i redeg sefydliad neu asiantaeth onid yw'r person hwnnw–

(a) yn unigolyn sy'n bodloni'r gofynion a bennir ym mharagraff (3); neu

(b) yn gorff, ac–

(i) y corff hwnnw wedi hysbysu swyddfa briodol yr awdurdod cofrestru o enw, cyfeiriad a swydd unigolyn yn y corff (sef yr unigolyn y cyfeirir ato yn y Rheoliadau hyn fel "yr unigolyn cyfrifol"), a'r unigolyn hwnnw'n gyfarwyddwr, rheolwr, ysgrifennydd neu swyddog arall y corff ac yn gyfrifol am oruchwylio rheolaeth y sefydliad neu'r asiantaeth; a

(ii) yr unigolyn hwnnw'n bodloni'r gofynion a bennir ym mharagraff (3).

(3) Y gofynion yw–

(a) bod yr unigolyn yn addas o ran ei uniondeb a'i gymeriad da i redeg y sefydliad neu'r asiantaeth neu, yn ôl fel y digwydd, i fod yn gyfrifol am oruchwylio rheolaeth y sefydliad neu'r asiantaeth;

(b) bod yr unigolyn yn ffit yn gorfforol ac yn feddyliol i redeg y sefydliad neu'r asiantaeth neu, yn ôl fel y digwydd, i fod yn gyfrifol am oruchwylio rheolaeth y sefydliad neu'r asiantaeth; ac

(c) bod gwybodaeth neu, yn ôl fel y digwydd, ddogfennaeth lawn a boddhaol, ar gael ynglŷn

regulations 38, 44 (7) and 48;

at intervals of not more than three years and, where appropriate, revise and implement those policies and procedures.

(6) The registered person must retain copies of all policies and procedures referred in this regulation, including previous versions of policies and procedures that have been revised in accordance with paragraph (5), for a period of not less than three years from the date of creation or revision of the policy or procedure.

(7) The registered person must make a copy of all written statements prepared in accordance with this regulation available for inspection by the registration authority.

## PART II

### Registered Persons

#### Fitness of registered provider

**10.**–(1) A person must not carry on an establishment or agency unless the person is fit to do so.

(2) A person is not fit to carry on an establishment or agency unless the person–

(a) is an individual who satisfies the requirements set out in paragraph (3); or

(b) is an organisation and–

(i) the organisation has given notice to the appropriate office of the registration authority of the name, address and position in the organisation of an individual (in these Regulations referred to as "the responsible individual") who is a director, manager, secretary or other officer of the organisation and is responsible for supervising the management of the establishment or agency; and

(ii) that individual satisfies the requirements set out in paragraph (3).

(3) The requirements are that–

(a) the individual is of suitable integrity and good character to carry on, or, as the case may be, be responsible for the supervision of the management of, the establishment or agency;

(b) the individual is physically and mentally fit to carry on, or, as the case may be, be responsible for the supervision of the management of, the establishment or agency; and

(c) full and satisfactory information or documentation, as the case may be, is available

â'r unigolyn mewn perthynas â phob un o'r materion a bennir ym mharagraffau 1, 2 a 4 i 8 o Atodlen 2.

(4) Nid yw person yn ffit i redeg sefydliad neu asiantaeth—

- (a) os yw'r person wedi'i farnu'n fethdalwr neu os dyfarnwyd atafaeliad ar ei ystâd ac nad yw'r person (yn y naill achos neu'r llall) wedi'i ryddhau, ac nad yw'r gorchymyn methdalwr wedi'i ddirymu na'i ddiddymu neu fod cyfnod o foratoriwm yn gymwys i'r person hwnnw o dan orchymyn rhyddhau o ddyled; neu
- (b) os yw'r person wedi gwneud compôwnd neu drefniant gyda chredydwy'r person hwnnw ac nad ydyw wedi'i ryddhau mewn perthynas â hynny.

### Penodi rheolwr

11.—(1) Rhaid i'r darparwr cofrestredig benodi unigolyn i reoli y sefydliad neu asiantaeth—

- (a) os nad oes rheolwr cofrestredig mewn perthynas â'r sefydliad neu asiantaeth; a
- (b) os yw'r darparwr cofrestredig—
  - (i) yn gorff;
  - (ii) yn berson nad yw'n ffit i reoli sefydliad neu asiantaeth; neu
  - (iii) yn berson nad yw'r sefydliad neu asiantaeth o dan ei ofal yn llawnamser o ddydd i ddydd, neu nad yw'n bwriadu i'r sefydliad neu'r asiantaeth fod o dan ei ofal felly.

(2) Os yw'r darparwr cofrestredig yn penodi person i reoli'r sefydliad neu'r asiantaeth, rhaid i'r darparwr cofrestredig hysbysu swyddfa briodol yr awdurdod cofrestru ar unwaith o'r canlynol—

- (a) enw'r person a benodwyd felly; a
- (b) y dyddiad y mae'r penodiad i ddod i rym.

(3) Os y darparwr cofrestredig sydd i reoli'r sefydliad neu asiantaeth rhaid iddo hysbysu swyddfa briodol yr awdurdod cofrestru ar unwaith o'r dyddiad y mae'r cyfryw reolaeth i ddechrau.

### Ffitrwydd y rheolwr

12.—(1) Rhaid i berson beidio â rheoli sefydliad neu asiantaeth onid yw'n berson ffit i wneud hynny.

(2) Nid yw person yn ffit i reoli sefydliad neu asiantaeth—

- (a) onid yw'n berson addas o ran ei uniondeb a'i gymeriad da i reoli'r sefydliad neu'r asiantaeth;
- (b) o ystyried maint y sefydliad neu asiantaeth, y

in relation to the individual in respect of each of the matters specified in paragraphs 1, 2 and 4 to 8 of Schedule 2.

(4) A person is not fit to carry on an establishment or agency if—

- (a) the person has been adjudged bankrupt or sequestration of the person's estate has been awarded and (in either case) the person has not been discharged and the bankruptcy order has not been annulled or rescinded or a moratorium period under a debt relief order applies in relation to the person; or
- (b) the person has made a composition or arrangement with the person's creditors and has not been discharged in respect of it.

### Appointment of manager

11.—(1) The registered provider must appoint an individual to manage the establishment or agency if—

- (a) there is no registered manager in respect of the establishment or agency; and
- (b) the registered provider—
  - (i) is an organisation;
  - (ii) is not a fit person to manage an establishment or agency; or
  - (iii) is not, or does not intend to be in full-time day to day charge of the establishment or agency.

(2) If the registered provider appoints a person to manage the establishment or agency, the registered provider must forthwith give notice to the appropriate office of the registration authority of—

- (a) the name of the person so appointed; and
- (b) the date on which the appointment is to take effect.

(3) If the registered provider is to manage the establishment or agency he or she must forthwith give notice to the appropriate office of the registration authority of the date on which such management is to begin.

### Fitness of manager

12.—(1) A person must not manage an establishment or agency unless the person is fit to do so.

(2) A person is not fit to manage an establishment or agency unless—

- (a) the person is of suitable integrity and good character to manage the establishment or agency;
- (b) having regard to the size of the establishment

datganiad o ddiben a niferoedd ac anghenion y cleifion—

- (i) onid oes gan y person y cymwysterau, y sgiliau a'r profiad angenrheidiol i reoli'r sefydliad neu'r asiantaeth; a
- (ii) onid yw'r person yn ffit yn gorfforol ac yn feddyliol i wneud hynny; ac
- (c) onid oes gwybodaeth neu, yn ôl fel y digwydd, ddogfennaeth lawn a boddhaol ar gael ynglŷn â'r person mewn perthynas â phob un o'r materion a bennir ym mharagraffau 1, 2 a 4 i 8 o Atodlen 2.

(3) Pan fo person yn rheoli mwy nag un sefydliad neu asiantaeth, rhaid iddo dreulio amser digonol ym mhob sefydliad neu asiantaeth i sicrhau y rheolir pob sefydliad neu asiantaeth yn effeithiol.

### Y person cofrestredig – gofynion cyffredinol

**13.**—(1) Rhaid i'r darparwr cofrestredig a'r rheolwr cofrestredig redeg neu reoli'r sefydliad neu asiantaeth, yn ôl fel y digwydd, gyda gofal, cymhwysedd a sgil digonol, o ystyried maint y sefydliad neu'r asiantaeth, y datganiad o ddiben a niferoedd ac anghenion y cleifion.

(2) Os yw'r darparwr cofrestredig—

- (a) yn unigolyn, rhaid iddo ymgymryd; neu
- (b) yn gorff, rhaid iddo sicrhau bod yr unigolyn cyfrifol yn ymgymryd,

o bryd i'w gilydd â pha bynnag hyfforddiant sy'n briodol i sicrhau bod ganddo'r sgiliau angenrheidiol i redeg y sefydliad neu asiantaeth.

(3) Rhaid i unrhyw unigolyn sy'n rheoli'r sefydliad neu asiantaeth ymgymryd, o bryd i'w gilydd, â pha bynnag hyfforddiant sy'n briodol i sicrhau bod ganddo'r sgiliau angenrheidiol i reoli'r sefydliad neu'r asiantaeth.

### Hysbysu ynghylch tramgyddau

**14.**—(1) Os caiff y person cofrestredig neu'r unigolyn cyfrifol ei gollfarnu am unrhyw dramgwydd troseddol, pa un ai yng Nghymru neu mewn man arall, rhaid i'r person a gollfarnwyd hysbysu swyddfa briodol yr awdurdod cofrestru mewn ysgriflen ar unwaith, o'r canlynol—

- (a) dyddiad a lleoliad y gollfarn;
- (b) y tramgwydd y collfarnwyd y person o'i herwydd; ac
- (c) y gosb a osodwyd ar y person mewn perthynas â'r tramgwydd.

(2) Os cyhuddir y person cofrestredig neu'r unigolyn cyfrifol o unrhyw dramgwydd y ceir gwneud gorchymyn mewn perthynas ag ef o dan Ran II o

or agency, the statement of purpose and the number and needs of the patients—

- (i) the person has the qualifications, skills and experience necessary to manage the establishment or agency; and
- (ii) the person is physically and mentally fit to do so; and
- (c) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in paragraphs 1, 2 and 4 to 8 of Schedule 2.

(3) Where a person manages more than one establishment or agency he or she must spend sufficient time at each establishment or agency to ensure that the establishment or agency is managed effectively.

### Registered person-general requirements

**13.**—(1) The registered provider and the registered manager must, having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients, carry on or manage the establishment or agency, as the case may be, with sufficient care, competence and skill.

(2) If the registered provider is—

- (a) an individual, he or she must undertake; or
- (b) an organisation, it must ensure that the responsible individual undertakes,

from time to time such training as is appropriate to ensure that he or she has the skills necessary for carrying on the establishment or agency.

(3) Any individual managing the establishment or agency must undertake from time to time such training as is appropriate to ensure that he or she has the skills necessary for managing the establishment or agency.

### Notification of offences

**14.**—(1) Where the registered person or the responsible individual is convicted of any criminal offence, whether in Wales or elsewhere, the person convicted must forthwith give notice in writing to the appropriate office of the registration authority of—

- (a) the date and place of the conviction;
- (b) the offence of which the person was convicted; and
- (c) the penalty imposed on the person in respect of the offence.

(2) Where the registered person or the responsible individual is charged with any offence in respect of which an order may be made under Part II of the

Ddeddf Cyfiawnder Troseddol a Gwasanaethau Llys 2000 (Amddiffyn Plant)(1) rhaid i'r person cofrestredig neu'r unigolyn cyfrifol hysbysu swyddfa briodol yr awdurdod cofrestru mewn ysgrifen ar unwaith, o'r tramgwydd y'i cyhuddwyd ohono, a dyddiad a lleoliad y cyhuddiad.

### RHAN III

Rhedeg Sefydliadau ac Asiantaethau Gofal Iechyd

#### Pennod 1

Ansawdd y Gwasanaeth a Ddarperir

#### Ansawdd y driniaeth a'r gwasanaethau eraill a ddarperir

15.–(1) Yn ddarostyngedig i reoliad 6(4), rhaid i'r person cofrestredig ddarparu unrhyw driniaethau a gwasanaethau eraill i gleifion yn unol â'r datganiad o ddiben a rhaid iddo sicrhau bod unrhyw driniaethau a gwasanaethau eraill a ddarperir i bob claf–

- (a) yn bodloni anghenion unigol y claf;
- (b) yn sicrhau lles a diogelwch y claf;
- (c) yn seiliedig ar dystiolaeth; ac
- (ch) y'u darperir (pan fo angen) gan ddefnyddio cyfarpar priodol.

(2) Rhaid i'r person cofrestredig sicrhau bod yr holl gyfarpar a ddefnyddir yn neu at ddibenion y sefydliad, neu at ddibenion yr asiantaeth, yn ddiogel, ac mewn cyflwr da ac yn addas at y dibenion y'i defnyddir ar eu cyfer.

(3) Pan ddefnyddir dyfeisiau meddygol ailddefnyddiadwy mewn sefydliad neu at ddibenion asiantaeth, rhaid i'r person cofrestredig sicrhau y dilynir gweithdrefnau priodol ar gyfer glanhau, diheintio, archwilio, pacio, sterileiddio, cludo a storio dyfeisiau o'r fath.

(4) Rhaid i'r gweithdrefnau a ddilynir yn unol â pharagraff (3) fod yn rhai sy'n sicrhau y caiff dyfeisiau meddygol ailddefnyddiadwy eu trin yn ddiogel a'u dadhalogi'n effeithiol cyn eu hailddefnyddio.

(5) Rhaid i'r person cofrestredig amddiffyn cleifion rhag y risgiau sy'n gysylltiedig â ffyrdd anniogel o ddefnyddio a rheoli meddyginiaethau, drwy–

- (a) gwneud trefniadau priodol ar gyfer caffael, cofnodi, trin, defnyddio, cadw'n ddiogel, dosbarthu, gweini a gwaredu meddyginiaethau yn ddiogel a ddefnyddir yn neu at ddibenion y sefydliad neu'r asiantaeth; a
- (b) rhoi sylw i unrhyw ganllawiau a ddyroddir gan yr awdurdod cofrestru neu gan gorff arbenigol

Criminal Justice and Court Services Act 2000 (Protection of Children)(1) the registered person or responsible individual must forthwith give notice in writing to the appropriate office of the registration authority of the offence charged and the date and place of the charge.

### PART III

Conduct of Health Care Establishments and Agencies

#### Chapter 1

Quality of Service Provision

#### Quality of treatment and other service provision

15.–(1) Subject to regulation 6(4), the registered person must provide any treatments and other services to patients in accordance with the statement of purpose, and must ensure that any treatments and other services provided to each patient–

- (a) meet the patient's individual needs;
- (b) ensure the welfare and safety of the patient;
- (c) are evidence based; and
- (d) are (where necessary) provided by means of appropriate equipment.

(2) The registered person must ensure that all equipment used in or for the purposes of the establishment or for the purposes of the agency is safe and in good condition and suitable for the purpose it is to be used for.

(3) Where reusable medical devices are used in an establishment or for the purposes of an agency, the registered person must ensure that appropriate procedures are implemented in relation to cleaning, disinfection, inspection, packaging, sterilisation, transportation and storage of such devices.

(4) The procedures implemented in accordance with paragraph (3) must be such as to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.

(5) The registered person must protect patients against the risks associated with the unsafe use and management of medicines, by means of–

- (a) the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used in or for the purposes of the establishment or agency; and
- (b) having regard to any guidance issued by the registration authority or appropriate expert

(1) 2000 p.43.

(1) 2000 c.43.

priodol ynglŷn â thrin a defnyddio meddyginiaethau yn ddiogel.

(6) Os defnyddir gwaed a chynhyrchion gwaed, rhaid i'r person cofrestredig sicrhau bod proses fonitro (haemo-wyliadwriaeth) wedi ei sefydlu i sicrhau diogelwch trallwysu gwaed.

(7) Rhaid i'r person cofrestredig, i'r graddau y bo'n rhesymol ymarferol, sicrhau y diogelir—

- (a) cleifion; a
- (b) eraill a allai fod mewn perygl o ddod i gysylltiad â haint sy'n gysylltiedig â gofal iechyd o ganlyniad i weithio mewn neu at ddibenion sefydliad neu asiantaeth,

rhag y risgiau canfyddadwy o gael haint o'r fath, drwy'r dulliau a bennir ym mharagraff (8).

(8) Y dulliau y cyfeirir atynt ym mharagraff (7) yw—

- (a) gweithredu'n effeithiol systemau a gynlluniwyd i asesu'r risg o heintiau sy'n gysylltiedig â gofal iechyd ac i'w hatal, eu canfod a'u rheoli;
- (b) pan fo'n gymwys, darparu triniaeth briodol i'r rhai yr effeithir arnynt gan haint sy'n gysylltiedig â gofal iechyd; ac
- (c) cynnal safonau priodol o lanweithdra a hylendid mewn perthynas ag—
  - (i) mangreoedd a feddiennir at y diben o gynnal y sefydliad neu'r asiantaeth;
  - (ii) cyfarpar a dyfeisiau meddygol ailddefnyddiadwy a ddefnyddir at y diben o gynnal y sefydliad neu'r asiantaeth; a
  - (iii) deunyddiau sydd i'w defnyddio wrth drin defnyddwyr y gwasanaeth, os oes risg y gallai deunyddiau o'r fath gael eu halogi gan haint sy'n gysylltiedig â gofal iechyd.

(9) Os yw sefydliad yn darparu bwyd a diod i gleifion fel cydran o'r gofal a roddir i'r cleifion, rhaid i'r person cofrestredig sicrhau—

- (a) bod anghenion y cleifion o ran maeth a'u hydradiad yn cael eu hasesu a'u dogfennu, wrth eu derbyn ac ar adegau rheolaidd wedi hynny;
- (b) y darperir bwyd a hydradu sy'n bodloni anghenion cleifion unigol o ran maeth a hydradiad.

(10) Rhaid i'r person cofrestredig roi sylw i unrhyw fwletinâu sy'n cynghori ynghylch y math o driniaeth a ddarperir gan y sefydliad neu'r asiantaeth, ac i'r wybodaeth am ddiogelwch cleifion a gyhoeddir gan gyrff rheoleiddio priodol, cyrff proffesiynol priodol neu gyrff arbenigol statudol priodol.

### **Diogelu cleifion rhag eu cam-drin**

16.–(1) Rhaid i'r person cofrestredig wneud

body in relation to the safe handling and use of medicines.

(6) The registered person must ensure that where blood and blood products are used a monitoring process for the safety of blood transfusion (haemovigilance) is in place.

(7) The registered person must, so far as reasonably practicable, ensure that—

- (a) patients; and
- (b) others who may be at risk of exposure to a health care associated infection arising from working in or for the purposes of an establishment or agency,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (8).

(8) The means referred to in paragraph (7) are—

- (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
- (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
- (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
  - (i) premises occupied for the purpose of carrying on the establishment or agency;
  - (ii) equipment and reusable medical devices used for the purpose of carrying on the establishment or agency; and
  - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

(9) If an establishment provides food and drink for patients as a component of the patients' care, the registered person must ensure that—

- (a) Patients' nutritional and hydration needs are assessed and documented on admission and at regular intervals thereafter;
- (b) Food and hydration is provided that meets individual patient nutritional and hydration needs.

(10) The registered person must take account of any advice bulletins relating to the type of treatment the establishment or agency provides and to patient safety information published by appropriate regulatory, professional or appropriate statutory expert bodies.

### **Safeguarding patients from abuse**

16.–(1) The registered person must make suitable

trefniadau addas i sicrhau y diogelir cleifion rhag y risg o'u cam-drin, drwy—

- (a) cymryd camau rhesymol i ganfod y posibilrwydd o gam-drin a'i atal cyn iddo ddigwydd; a
- (b) ymateb yn briodol i unrhyw honiad o gam-drin.

(2) Os defnyddir unrhyw ffurf o reolaeth neu ataliad mewn sefydliad neu at ddibenion asiantaeth, rhaid i'r person cofrestredig fod wedi sefydlu trefniadau addas i ddiogelu cleifion rhag y risg y gallai'r cyfryw reolaeth neu ataliad fod—

- (a) yn anghyfreithlon; neu
- (b) yn ormodol rywfodd arall.

(3) Rhaid i'r person cofrestredig roi sylw i unrhyw ganllawiau a ddyroddir gan yr awdurdod cofrestru neu gorff arbenigol priodol mewn perthynas ag—

- (a) amddiffyn plant ac oedolion hygllwyf yn gyffredinol; a
- (b) yn benodol, defnydd priodol o ddulliau rheoli neu atal.

(4) At ddibenion paragraff (1), ystyr "cam-drin" ("*abuse*"), mewn perthynas â chlaf, yw—

- (a) cam-drin yn rhywiol;
- (b) camdriniaeth gorfforol neu seicolegol;
- (c) lladrata, camdefnyddio neu gamberchnogi arian neu eiddo; neu
- (ch) esgeulustod ac anweithiau sy'n achosi niwed neu'n peri risg o niwed i'r claf.

### Galluedd cleifion

17.—(1) Rhaid i'r person cofrestredig, i'r graddau y mae'n ymarferol, ac os nad oes galluedd gan y claf, yn unol ag egwyddorion Deddf 2005, alluogi pob claf i wneud penderfyniadau ynglŷn â materion sy'n effeithio ar y modd y gofelig am y claf ac am ei les.

(2) Rhaid i'r person cofrestredig sicrhau y galluogir i gleifion reoli eu harian eu hunain ac eithrio pan nad yw'r claf yn dymuno gwneud hynny neu pan nad oes ganddo'r galluedd i wneud hynny, ac mewn achos o'r fath rhaid i'r person cofrestredig sicrhau y delir ac y cofnodir arian y claf yn briodol, ac y dyroddir derbynebion fel y bo'n briodol.

(3) Rhaid i'r person cofrestredig, i'r graddau y mae'n ymarferol, ac os nad oes galluedd gan y cleifion, yn unol ag egwyddorion Deddf 2005, ganfod a chymryd i ystyriaeth ddymuniadau a theimladau pob un o'r cleifion wrth benderfynu ar y modd y gofelig amdanynt ac y darperir gwasanaethau iddynt.

arrangements to ensure that patients are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the establishment or for the purposes of an agency, the registered person must have suitable arrangements in place to protect patients against the risk of such control or restraint being—

- (a) unlawful; or
- (b) otherwise excessive.

(3) The registered person must have regard to any guidance issued by the registration authority or appropriate expert body, in relation to—

- (a) the protection of children and vulnerable adults generally; and
- (b) in particular, the appropriate use of methods of control or restraint.

(4) For the purposes of paragraph (1), "abuse" ("*cam-drin*"), in relation to a patient, means—

- (a) sexual abuse;
- (b) physical or psychological ill-treatment;
- (c) theft, misuse or misappropriation of money or property; or
- (d) neglect and acts of omission which cause harm or place at risk of harm.

### Capacity of patients

17.—(1) The registered person must, so far as is practicable, and, where the patient lacks capacity, in accordance with the principles of the 2005 Act enable each patient to make decisions about matters affecting the way in which the patient is cared for and his or her welfare.

(2) The registered person must ensure that patients are enabled to control their own money, except where a patient does not wish, or lacks capacity to do so, in which case the registered person must ensure that patient monies are properly held and recorded and that receipts are issued as appropriate.

(3) The registered person must so far as practicable, and where patients lack capacity, in accordance with the principles of the 2005 Act ascertain and take into account the wishes and feelings of all patients in determining the manner in which they are cared for and services are provided to them.

## **Preifatrwydd, urddas a pherthnasau**

**18.**–(1) Rhaid i'r person cofrestredig wneud trefniadau addas i sicrhau y caiff y sefydliad ei redeg, neu'r asiantaeth ei rhedeg–

- (a) mewn modd sy'n parchu preifatrwydd ac urddas y cleifion; a
- (b) gan roi sylw priodol i ryw, argyhoeddiad crefyddol, tarddiad hiliol, cyfeiriadedd rhywiol a chefnidir diwylliannol ac ieithyddol y cleifion, ac unrhyw anabledd sydd ganddynt.

(2) Rhaid i'r person cofrestredig a'r rheolwr cofrestredig (os oes un) ill dau gymryd pob cam rhesymol i sicrhau y caiff y sefydliad ei redeg, neu'r asiantaeth ei rhedeg ar sail perthnasau personol a phroffesiynol da–

- (a) rhwng y naill a'r llall; a
- (b) rhwng pob un ohonynt a'r cleifion a'r staff.

## **Asesu a monitro ansawdd y ddarpariaeth o wasanaethau, gan gynnwys datganiadau blynyddol**

**19.**–(1) Rhaid i'r person cofrestredig ddiogelu cleifion, ac eraill a allai fod yn wynebu risg, rhag y risgiau o gael gofal a thriniaeth amhriodol neu annïogel, drwy weithredu'n effeithiol systemau a gynlluniwyd i alluogi'r person cofrestredig i–

- (a) asesu a monitro'n rheolaidd ansawdd y gwasanaethau a ddarperir wrth redeg y sefydliad neu asiantaeth, gyferbyn â'r gofynion a bennir yn y Rheoliadau hyn; a
- (b) canfod, asesu a rheoli risgiau mewn cysylltiad ag iechyd, lles a diogelwch cleifion ac eraill.

(2) At ddibenion paragraff (1), rhaid i'r person cofrestredig–

- (a) pan fo'n briodol, cael cyngor proffesiynol perthnasol;
- (b) rhoi sylw i–
  - (i) y cwynion a'r sylwadau a wneir a'r safbwyntiau a fynegir (gan gynnwys y disgrifiadau o'u profiadau o ofal a thriniaeth) gan gleifion a rhai sy'n gweithredu ar eu rhan, yn unol ag is-baragraff (d) a rheoliad 24;
  - (ii) unrhyw ymchwiliad a gyflawnir gan y person cofrestredig mewn perthynas ag ymddygiad person a gyflogir at y diben o redeg y sefydliad neu'r asiantaeth;
  - (iii) yr wybodaeth a gynhwysir yn y cofnodion y cyfeirir atynt yn rheoliad 23;
  - (iv) cyngor proffesiynol ac arbenigol priodol (gan gynnwys unrhyw gyngor a geir yn unol ag is-baragraff (a));
  - (v) adroddiadau a baratoir gan yr awdurdod

## **Privacy, dignity and relationships**

**18.**–(1) The registered person must make suitable arrangements to ensure that the establishment or agency is conducted–

- (a) in a manner which respects the privacy and dignity of patients; and
- (b) with due regard to the sex, religious persuasion, racial origin, sexual orientation, cultural and linguistic background and any disability of patients.

(2) The registered provider and the registered manager (if any) must each take all reasonable steps to ensure that the establishment or agency is conducted on the basis of good personal and professional relationships–

- (a) between each other; and
- (b) between each of them and the patients and staff.

## **Assessing and monitoring the quality of service provision including annual returns**

**19.**–(1) The registered person must protect patients, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to–

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the establishment or agency against the requirements set out in these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of patients and others.

(2) For the purposes of paragraph (1), the registered person must–

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to–
  - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by patients, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 24;
  - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the establishment or agency;
  - (iii) the information contained in the records referred to in regulation 23;
  - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a));
  - (v) reports prepared by the registration

cofrestru o bryd i'w gilydd yn unol ag adran 32(5) o'r Ddeddf mewn perthynas â'r sefydliad neu'r asiantaeth;

- (c) pan fo angen, gwneud newidiadau yn y driniaeth neu'r gofal a ddarperir, er mwyn adlewyrchu gwybodaeth y gellir disgwyl yn rhesymol y byddai person cofrestredig yn ymwybodol ohoni, mewn perthynas ag—
  - (i) dadansoddi digwyddiadau a achosodd, neu a oedd â'r potensial i achosi, niwed i glaf; a
  - (ii) casgliadau'r adolygiadau lleol a chenedlaethol o'r gwasanaeth, archwiliadau clinigol a phrosiectau ymchwil a ymgymerir gan gyrff arbenigol priodol;
- (ch) sefydlu mecanweithiau i sicrhau y gwneir y penderfyniadau ynglŷn â'r ddarpariaeth o ofal a thriniaeth i gleifion ar y lefel briodol, a chan berson priodol; a
- (d) holi'n rheolaidd ynghylch safbwyntiau (gan gynnwys disgrifiadau o'u profiadau o ofal a thriniaeth) cleifion, personau sy'n gweithredu ar eu rhan, personau a gyflogir at ddibenion y sefydliad neu asiantaeth ac unrhyw ymarferydd meddygol sydd â breintiau ymarfer, i alluogi'r person cofrestredig i ffurfio barn wybodus ynglŷn â safon y gofal a thriniaeth a ddarperir i'r cleifion.

(3) Pan ofynnir iddo wneud hynny, rhaid i'r person cofrestredig anfon i swyddfa briodol yr awdurdod cofrestru asesiad blynyddol ysgrifenedig (y cyfeirir ato fel y "datganiad blynyddol") a fydd yn nodi sut, ac i ba raddau, ym marn y person cofrestredig, y cydymffurfir â gofynion paragraff (1) mewn perthynas â'r sefydliad neu'r asiantaeth, ynghyd ag unrhyw gynlluniau sydd gan y person cofrestredig ar gyfer gwella safon y gwasanaethau a ddarperir i gleifion, gyda golwg ar sicrhau eu hiechyd a'u lles.

(4) Rhaid i'r person cofrestredig gymryd camau rhesymol i sicrhau nad yw'r datganiad blynyddol yn gamarweiniol neu'n anghywir.

(5) Rhaid i'r person cofrestredig gyflenwi'r datganiad blynyddol i swyddfa briodol yr awdurdod cofrestru o fewn 28 diwrnod ar ôl cael cais o dan baragraff (3).

## Staffio

20.–(1) Rhaid i'r person cofrestredig, gan ystyried natur y sefydliad neu'r asiantaeth, y datganiad o ddiben a nifer ac anghenion y cleifion—

- (a) sicrhau bod personau â chymwysterau, sgiliau a phrofiad addas bob amser yn gweithio yn,

authority from time to time pursuant to section 32(5) of the Act in relation to the establishment or agency;

- (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
  - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a patient; and
  - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;
- (d) establish mechanisms for ensuring that decisions in relation to the provision of care and treatment for patients are taken at the appropriate level and by an appropriate person; and
- (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of patients, persons acting on their behalf, persons who are employed for the purposes of the establishment or agency and any medical practitioner with practising privileges, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to patients.

(3) The registered person must send to the appropriate office of the registration authority, when requested to do so, a written annual assessment (referred to as the "annual return") setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with in relation to the establishment or agency, together with any plans that the registered person has for improving the standard of the services provided to patients with a view to ensuring their health and welfare.

(4) The registered person must take reasonable steps to ensure that the annual return is not misleading or inaccurate.

(5) The registered person must supply the annual return to the appropriate office of the registration authority within 28 days of receiving a request under paragraph (3).

## Staffing

20.–(1) The registered person must, having regard to the nature of the establishment or agency, the statement of purpose and the number and needs of patients—

- (a) ensure that at all times suitably qualified, skilled and experienced persons are working in



neu at ddibenion y sefydliad neu, yn ôl fel y digwydd, at ddibenion yr asiantaeth, a bod eu niferoedd yn briodol ar gyfer iechyd a lles y cleifion;

- (b) sicrhau na fydd cyflogi unrhyw bersonau dros dro yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth yn rhwystro cleifion rhag cael parhad gofal o'r fath sy'n rhesymol i ddiwallu eu hanghenion.

(2) Rhaid i'r person cofrestredig sicrhau bod pob person a gyflogir yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth—

- (a) yn cael hyfforddiant, goruchwyliaeth a gwerthusiad priodol;
- (b) yn cael ei alluogi o bryd i'w gilydd i ennill cymwysterau pellach sy'n briodol i'r gwaith y mae'r person yn ei gyflawni; ac
- (c) yn cael ei ddarparu â disgrifiad swydd sy'n amlinellu cyfrifoldebau'r person.

(3) Rhaid i'r person cofrestredig sicrhau bod pob person a gyflogir yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth ac unrhyw ymarferydd meddygol â breintiau ymarfer, yn cael eu gwerthuso yn rheolaidd ac yn briodol, a rhaid iddo gymryd unrhyw gamau sy'n angenrheidiol i fynd i'r afael ag unrhyw agwedd—

- (a) ar ymarfer clinigol proffesiynolyn gofal iechyd; neu
- (b) ar berfformiad aelod o'r staff nad yw'n broffesiynolyn gofal iechyd,

y cafwyd ei fod yn anfodddhaol.

(4) Rhaid i'r person cofrestredig gymryd camau rhesymol i sicrhau bod unrhyw bersonau sy'n gweithio yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth, nad ydynt yn cael eu cyflogi gan y person cofrestredig ac nad yw paragraff (2) yn gymwys iddynt, yn cael eu goruchwyllo'n briodol tra bônt yn cyflawni eu swyddogaethau, er mwyn sicrhau na pheryglir iechyd a lles y cleifion.

### **Ffitrwydd y gweithwyr**

21.—(1) Yn ddarostyngedig i baragraff (4), rhaid i'r person cofrestredig beidio â gwneud y canlynol—

- (a) cyflogi person o dan gonacontract cyflogi i weithio yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth onid yw'r person hwnnw yn ffit i wneud hynny;
- (b) caniatáu i wirfoddolwr weithio yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth onid yw'r person hwnnw yn ffit i wneud hynny;
- (c) caniatáu i unrhyw berson arall (gan gynnwys ymarferydd meddygol sy'n gwneud cais am gael breintiau ymarfer) weithio yn neu ar ran y

or for the purposes of the establishment or as the case may be, for the purposes of the agency, in such numbers as are appropriate for the health and welfare of the patients;

- (b) ensure that the employment of any persons on a temporary basis in or for the purposes of the establishment or for the purposes of the agency will not prevent patients from receiving such continuity of care as is reasonable to meet their needs.

(2) The registered person must ensure that each person employed in or for the purposes of the establishment, or for the purposes of the agency—

- (a) receives appropriate training, supervision and appraisal;
- (b) is enabled from time to time to obtain further qualifications appropriate to the work the person performs; and
- (c) is provided with a job description outlining the person's responsibilities.

(3) The registered person must ensure that each person employed in or for the purposes of the establishment or for the purposes of the agency and any medical practitioner with practising privileges, receives regular and appropriate appraisal and must take such steps as may be necessary to address any aspect of—

- (a) a health care professional's clinical practice; or
- (b) the performance of a member of staff who is not a health care professional,

which is found to be unsatisfactory.

(4) The registered person must take reasonable steps to ensure that any persons working in or for the purposes of an establishment or for the purposes of an agency who are not employed by the registered person and to whom paragraph (2) does not apply, are appropriately supervised to ensure patients' health and welfare is not compromised, while carrying out their duties.

### **Fitness of workers**

21.—(1) Subject to paragraph (4) the registered person must not—

- (a) employ under a contract of employment a person to work in or for the purposes of the establishment or for the purposes of the agency unless that person is fit to do so;
- (b) allow a volunteer to work in or for the purposes of the establishment or for the purposes of the agency unless that person is fit to do so;
- (c) allow any other person (including a medical practitioner seeking the grant of practising privileges) to work in or for the establishment

sefydliad neu at ddibenion yr asiantaeth mewn swydd lle y gallai ddod i gysylltiad rheolaidd â chlaf wrth gyflawni ei ddyletswyddau onid yw'r person hwnnw yn ffit i weithio yn neu ar ran y sefydliad neu at ddibenion yr asiantaeth.

(2) At ddibenion paragraff (1) nid yw person yn ffit i weithio yn neu ar ran sefydliad neu at ddibenion asiantaeth oni bai—

- (a) bod y person yn addas o ran ei uniondeb a'i gymeriad da ar gyfer y gwaith y mae'r person i'w gyflawni;
- (b) bod gan y person y cymwysterau, y sgiliau a'r profiad angenrheidiol ar gyfer y gwaith hwnnw;
- (c) bod y person yn ffit yn gorfforol ac yn feddyliol ar gyfer y gwaith hwnnw; ac
- (ch) bod gwybodaeth neu, yn ôl fel y digwydd, ddogfennaeth, lawn a boddhaol ar gael ynglŷn â'r person mewn perthynas â phob un o'r materion a bennir ym mharagraffau 1 a 3 i 8 o Atodlen 2.

(3) Rhaid i'r person cofrestredig, neu berson ar ran y person cofrestredig wneud cais am y dystysgrif y cyfeirir ati ym mharagraff 3 o Atodlen 2, at ddiben asesu addarwydd person i'r swydd y cyfeirir ati ym mharagraff (1).

(4) Rhaid i'r person cofrestredig sicrhau—

- (a) bod unrhyw gynnig o gyflogaeth a wneir i berson a ddisgrifir ym mharagraff (1), neu drefniant arall ynghylch gweithio yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth a wneir gyda'r person hwnnw neu mewn perthynas ag ef, yn ddarostyngedig i gydymffurfio â pharagraff (2)(ch) mewn perthynas â'r person hwnnw; a
- (b) oni fydd paragraff (5) yn gymwys, na fydd unrhyw berson o'r fath yn dechrau gweithio yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth hyd nes cydymffurfir â pharagraff (2)(ch) mewn perthynas â'r person hwnnw.

(5) Pan fo'r amodau canlynol yn gymwys, caiff y person cofrestredig ganiatáu i berson nad yw'n broffesiynolyn gofal iechyd ddechrau gweithio yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth er gwaethaf paragraffau (1) a (4)(b)—

- (a) bod y person cofrestredig wedi cymryd pob cam rhesymol i sicrhau gwybodaeth lawn ynghylch pob mater a restrir ym mharagraffau 1 a 3 i 8 o Atodlen 2 ynglŷn â'r person hwnnw, ond bod yr ymholiadau mewn perthynas ag unrhyw un o'r materion a restrir ym mharagraffau 4 i 8 o Atodlen 2 yn anghyflawn;
- (b) bod gwybodaeth lawn a boddhaol mewn perthynas â'r person hwnnw wedi'i sicrhau ynghylch y materion a bennir ym mharagraffau 1 a 3 o Atodlen 2;

or for the purposes of the agency in a position in which he or she may in the course of his or her duties have regular contact with a patient unless that person is fit to work in or for the establishment or for the purposes of the agency.

(2) For the purposes of paragraph (1) a person is not fit to work in or for the purposes of an establishment or for the purposes of an agency unless—

- (a) the person is of suitable integrity and good character for the work which the person is to perform;
- (b) the person has the qualifications, skills and experience which are necessary for that work;
- (c) the person is physically and mentally fit for that work; and
- (d) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.

(3) The certificate referred to in paragraph 3 of Schedule 2 must be applied for by, or on behalf of the registered person, for the purpose of assessing the suitability of a person for the post referred to in paragraph (1).

(4) The registered person must ensure that—

- (a) any offer of employment to, or other arrangement about working in or for the purposes of the establishment or for the purposes of the agency made with or in respect of a person described in paragraph (1) is subject to paragraph (2)(d) being complied with in relation to that person; and
- (b) unless paragraph (5) applies, no such person starts work in or for the purposes of the establishment or for the purposes of the agency until such time as paragraph (2)(d) has been complied with in relation to that person.

(5) Where the following conditions apply, the registered person may permit a person other than a health care professional to start work in or for the purposes of the establishment or for the purposes of an agency notwithstanding paragraphs (1) and (4)(b)—

- (a) the registered person has taken all reasonable steps to obtain full information in respect of each of the matters listed in paragraphs 1 and 3 to 8 of Schedule 2 in respect of that person, but the enquiries in relation to any of the matters listed in paragraphs 4 to 8 of Schedule 2 are incomplete;
- (b) full and satisfactory information in relation to that person has been obtained in respect of the matters specified in paragraphs 1 and 3 of Schedule 2;

- (c) bod yr amgylchiadau yn eithriadol ym marn resymol y person cofrestredig; ac
- (ch) hyd nes y caiff, ac y'i bodlonir gan, unrhyw wybodaeth sydd heb ddod i law, bod y person cofrestredig yn sicrhau bod y person yn cael ei oruchwylio'n briodol tra'n cyflawni ei ddyletswyddau.

(6) Rhaid i'r person cofrestredig sicrhau bod unrhyw berson sy'n gweithio yn, neu at ddibenion y sefydliad neu asiantaeth ac nad yw'n dod o fewn paragraff (1) yn cael ei oruchwylio'n briodol drwy gydol yr amser pan fo mewn cysylltiad â chleifion.

### Canllawiau ar gyfer proffesiynolion gofal iechyd

22. Rhaid i'r person cofrestredig sicrhau bod unrhyw god moeseg neu god ymarfer proffesiynol, a baratoir gan gorff sy'n gyfrifol am reoleiddio aelodau o broffesiwn gofal iechyd, ar gael yn y sefydliad neu'r asiantaeth i aelodau'r proffesiwn gofal iechyd dan sylw.

### Cofnodion

23.–(1) Rhaid i'r person cofrestredig sicrhau, ac eithrio mewn achosion pan fo rheoliad 43(5) yn gymwys–

- (a) bod cofnod gofal iechyd cynhwysfawr yn cael ei gadw, ar bapur neu mewn ffurf electronig, mewn perthynas â phob claf, a'i fod yn cynnwys–
  - (i) nodyn cyfoes o bob triniaeth a ddarperir i'r claf;
  - (ii) hanes meddygol y claf a phob nodyn arall a baratoir gan broffesiynolyn gofal iechyd ynghylch achos y claf; a
- (b) y delir gafaal ar y cofnod am gyfnod na fydd yn llai na'r cyfnod a bennir yn Rhan I o Atodlen 3 mewn perthynas â'r math o glaf sydd dan sylw, neu, os gall rhagor nag un cyfnod o'r fath fod yn gymwys, yr hwyaf ohonynt.

(2) Rhaid i'r person cofrestredig sicrhau–

- (a) bod cofnod gofal iechyd person sydd ar hyn o bryd yn glaf yn cael ei gadw mewn lle diogel ym mangre'r sefydliad neu'r asiantaeth; a
- (b) bod cofnod gofal iechyd person nad yw ar hyn o bryd yn glaf yn cael ei storio'n ddiogel (pa un ai yn y sefydliad neu'r asiantaeth neu mewn man arall) a bod modd dod o hyd iddo pe bai angen.

(3) Yn ychwanegol at y cofnodion gofal iechyd a gedwir yn unol â pharagraff (1), rhaid i'r person cofrestredig sicrhau y cedwir, ar bapur neu mewn ffurf electronig, y cofnodion a bennir yn Rhan II o Atodlen 3 ac–

- (c) in the reasonable opinion of the registered person the circumstances are exceptional; and
- (d) pending receipt of, and being satisfied with regard to, any outstanding information, the registered person ensures that the person is appropriately supervised while carrying out his or her duties.

(6) The registered person must ensure that any person working in or for the purposes of the establishment or agency who does not fall within paragraph (1) is appropriately supervised at all times when they are in contact with patients.

### Guidance for health care professionals

22. The registered person must ensure that any code of ethics or professional practice prepared by a body which is responsible for regulation of members of a health care profession is made available in the establishment or agency to members of the health care profession in question.

### Records

23.–(1) The registered person must ensure that except in cases to which regulation 43(5) applies–

- (a) a comprehensive health care record which may be in paper or electronic form is maintained in relation to each patient, which includes–
  - (i) a contemporaneous note of all treatment provided to the patient;
  - (ii) the patient's medical history and all other notes prepared by a health care professional about the patient's case; and
- (b) the record is retained for a period which is not less than that specified in Part I of Schedule 3 in relation to the type of patient in question or, where more than one such period could apply, the longest of them.

(2) The registered person must ensure that–

- (a) the health care record for a person who is currently a patient is kept in a secure place in the establishment or agency premises; and
- (b) the health care record for a person who is not currently a patient is stored securely (whether in the establishment or agency or elsewhere) and that it can be located if required.

(3) In addition to the health care records maintained in accordance with paragraph (1), the registered person must ensure that the records, which may be in paper or electronic form, specified in Part II of Schedule 3 are maintained and that they are–

- (a) eu bod yn cael eu diweddarau;
- (b) eu bod ar gael bob amser yn y sefydliad neu'r asiantaeth i'w harchwilio gan unrhyw berson a awdurdodir gan yr awdurdod cofrestru i fynd i mewn i'r sefydliad i'w archwilio neu i'r asiantaeth i'w harchwilio; ac
- (c) y delir gafael arnynt am gyfnod o ddim llai na thair blynedd, sy'n cychwyn ar ddyddiad y cofnod olaf.

(4) Os bydd sefydliad neu asiantaeth yn cau, rhaid i'r person cofrestredig sicrhau bod y cofnodion a gedwir yn unol â pharagraffau (1) a (3) yn cael eu storio'n ddiogel mewn man arall a rhaid iddo drefnu iddynt fod ar gael i'w harchwilio gan yr awdurdod cofrestru os bydd yr awdurdod yn gofyn amdanynt.

### Cwynion

24.–(1) Rhaid i'r person cofrestredig sefydlu gweithdrefn (y cyfeirir ati yn y Rheoliadau hyn fel "y weithdrefn gwyno") ar gyfer ystyried cwynion a wneir i'r person cofrestredig gan glaf neu berson sy'n gweithredu ar ran claf.

(2) Rhaid i'r person cofrestredig sicrhau yr ymchwiliwr yn llawn i unrhyw gŵyn a wneir o dan y weithdrefn gwyno.

(3) Os gofynnir amdano, rhaid i'r person cofrestredig ddarparu copi ysgrifenedig o'r weithdrefn gwyno–

- (a) i bob claf;
- (b) i unrhyw berson sy'n gweithredu ar ran claf; ac
- (c) i unrhyw berson sy'n ystyried dod yn glaf.

(4) Rhaid i'r copi ysgrifenedig o'r weithdrefn gwyno gynnwys–

- (a) enw, cyfeiriad a rhif teleffon swyddfa briodol yr awdurdod cofrestru; a
- (b) y weithdrefn (os oes un) yr hysbyswyd y person cofrestredig ohoni gan yr awdurdod cofrestru, ar gyfer cwyno wrth yr awdurdod cofrestru ynghylch y sefydliad neu'r asiantaeth.

(5) Rhaid i'r person cofrestredig gadw cofnod o bob cwyn, gan gynnwys manylion yr ymchwiliadau a wnaed, y canlyniad ac unrhyw gamau a gymerwyd yn sgil hynny, gan gynnwys pa un a oes angen gweithredu ai peidio i wella ansawdd y driniaeth neu'r gwasanaethau, a bydd gofynion rheoliad 23(3)(b) ac (c) yn gymwys i'r cofnod hwnnw.

(6) Rhaid i'r person cofrestredig ddarparu copiâu i'r awdurdod cofrestru o'r cofnodion a gedwir o dan baragraff (5), os gofynnir amdanynt gan yr awdurdod.

- (a) kept up to date;
- (b) at all times available for inspection in the establishment or agency by any person authorised by the registration authority to enter and inspect the establishment or agency; and
- (c) retained for a period of not less than three years beginning on the date of the last entry.

(4) Where an establishment or agency closes the registered person must ensure that the records maintained in accordance with paragraphs (1) and (3) are kept securely elsewhere and must make them available for inspection by the registration authority at its request.

### Complaints

24.–(1) The registered person must establish a procedure (in these Regulations referred to as "the complaints procedure") for considering complaints made to the registered person by a patient or a person acting on behalf of a patient.

(2) The registered person must ensure that any complaint made under the complaints procedure is fully investigated.

(3) The registered person must supply a written copy of the complaints procedure upon request, to–

- (a) every patient;
- (b) any person acting on behalf of a patient; and
- (c) any person who is considering whether to become a patient.

(4) The written copy of the complaints procedure must include–

- (a) the name, address and telephone number of the appropriate office of the registration authority; and
- (b) the procedure (if any) which has been notified by the registration authority to the registered person for making complaints to the registration authority relating to the establishment or agency.

(5) The registered person must maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence including whether any action is necessary to improve the quality of treatment or services and the requirements of regulation 23(3)(b) and (c) will apply to that record.

(6) The registered person must supply to the registration authority at its request copies of records maintained under paragraph (5).

## Ymchwil

25.–(1) Rhaid i'r person cofrestredig sicrhau–

- (a) cyn ymgymryd, mewn sefydliad neu at ddibenion sefydliad, ag unrhyw ymchwil sy'n ymwneud â chleifion, gwybodaeth am gleifion, neu feinweoedd dynol, bod cynnig ymchwil yn cael ei baratoi ac y caiff ei gymeradwyo gan y Pwyllgor Moeseg Ymchwil priodol; a
- (b) bod pob prosiect ymchwil o'r fath yn cynnwys camau digonol i ddiogelu cleifion a chyflogeion.

(2) At ddibenion paragraff (1)(a), ystyr "y Pwyllgor Moeseg Ymchwil priodol" ("*the appropriate Research Ethics Committee*") yw pwyllgor moeseg ymchwil a sefydlir yn unol â chanllawiau a ddyroddir o bryd i'w gilydd gan yr awdurdod cofrestru neu gorff arbenigol priodol.

Pennod 2  
Mangreoedd

## Ffitrwydd y fangre

26.–(1) Rhaid i'r person cofrestredig beidio â defnyddio mangre at ddibenion sefydliad neu asiantaeth oni fydd y fangre honno mewn lleoliad, ac o ddyluniad a chynllun ffisegol, sy'n addas at y diben o gyflawni'r nodau ac amcanion a bennir yn y datganiad o ddiben.

(2) Rhaid i'r person cofrestredig sicrhau–

- (a) bod y fangre'n darparu amgylchedd glân, diogel a diddos yn unol â'r ddeddfwriaeth a'r arferion gorau cyfredol;
- (b) bod y fangre o adeiladwaith cadarn ac y'i cedwir mewn cyflwr da yn allanol ac yn fewnol;
- (c) bod maint a chynllun y sefydliad yn addas at y dibenion y maent i'w defnyddio ar eu cyfer a'u bod wedi'u cyfarparu a'u dodrefnu'n addas;
- (ch) os ymgymerir â gweithdrefnau llawfeddygol, os defnyddir systemau cynnal bywyd, neu os darperir gwasanaethau obstetrig a gwasanaethau meddygol mewn cysylltiad â geni plant yn y sefydliad, y darperir pa bynnag gyflenwad trydan y byddai ei angen i ddiogelu bywydau'r cleifion.

(3) Rhaid i'r person cofrestredig ddarparu'r canlynol i gyflogeion ac i ymarferwyr meddygol sydd â breintiau ymarfer–

- (a) cyfleusterau a llety addas, ac eithrio llety cysgu, gan gynnwys–
  - (i) cyfleusterau ar gyfer newid; a
  - (ii) cyfleusterau storio; a
- (b) pan fo angen darparu llety o'r fath ar

## Research

25.–(1) The registered person must ensure that–

- (a) before any research involving patients, information about patients, or human tissue is undertaken in or for the purposes of an establishment, a research proposal is prepared and approval is obtained from the appropriate Research Ethics Committee; and
- (b) all such research projects include adequate safeguards for patients and employees.

(2) For the purposes of paragraph (1)(a), "the appropriate Research Ethics Committee" ("*y Pwyllgor Moeseg Ymchwil priodol*") means a research ethics committee established in accordance with guidance issued from time to time by the registration authority or appropriate expert body.

Chapter 2  
Premises

## Fitness of premises

26.–(1) The registered person must not use premises for the purposes of an establishment or agency unless those premises are in a location and of a physical design and layout, which are suitable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person must ensure that–

- (a) the premises provide a clean, safe and secure environment in accordance with current legislation and best practice;
- (b) the premises are of sound construction and kept in a good state of repair externally and internally;
- (c) the size and layout of the establishment is suitable for the purposes for which they are used and are suitably equipped and furnished;
- (d) if surgical procedures are undertaken, life support systems are used, or obstetric services and, in connection with childbirth, medical services, are provided in the establishment, such electrical supply is provided during the interruption of public supply as is needed to safeguard the lives of the patients.

(3) The registered person must provide for employees and medical practitioners with practising privileges –

- (a) suitable facilities and accommodation, other than sleeping accommodation, including–
  - (i) facilities for the purpose of changing; and
  - (ii) storage facilities; and
- (b) where the provision of such accommodation is

gyflogeion mewn cysylltiad â'u gwaith, llety cysgu.

(4) Yn ddarostyngedig i baragraff 5, rhaid i'r person cofrestredig—

- (a) cymryd rhagofalon digonol yn erbyn y risg o dân, gan gynnwys darparu a chynnal cyfarpar digonol i atal a chanfod tân;
- (b) darparu moddion dianc digonol, i'w defnyddio pe digwyddai tân;
- (c) gwneud trefniadau i bersonau a gyflogir yn y sefydliad, ac i ymarferwyr meddygol y rhoddwyd breintiau ymarfer iddynt, gael hyfforddiant addas mewn atal tân;
- (ch) sicrhau, drwy gyfrwng driliau ac ymarferion tân a gynhelir o bryd i'w gilydd fel y bo'n addas, fod y personau a gyflogir yn y sefydliad, ac i'r graddau y bo'n ymarferol, y cleifion a'r ymarferwyr meddygol y rhoddwyd breintiau ymarfer iddynt, yn gyfarwydd â'r weithdrefn sydd i'w dilyn os digwydd tân;
- (d) adolygu, fesul cyfnod o ddim mwy na deuddeng mis, y rhagofalon tân, addasrwydd y cyfarpar tân a'r weithdrefn sydd i'w dilyn os digwydd tân; ac
- (dd) paratoi asesiad risg ysgrifenedig ar gyfer diogelwch tân.

(5) Pan fo Gorchymyn Diwygio Rheoleiddio (Diogelwch Tân) 2005(1) yn gymwys i'r fangre—

- (a) nid yw paragraff (4) yn gymwys; a
- (b) rhaid i'r person cofrestredig sicrhau y cydymffurfir, mewn perthynas â'r fangre honno, â gofynion y Gorchymyn hwnnw ac unrhyw reoliadau a wnaed odano ac eithrio erthygl 23 (dyletswyddau cyflogeion).

### **Ffitrwydd y fangre – anabledd dysgu**

27.—(1) Yn ddarostyngedig i reoliad 53—

- (a) rhaid i'r person cofrestredig sicrhau na chaiff ysbyty annibynnol sy'n darparu neu'n bwriadu darparu llety dros nos —
  - (i) am gyfnod o 12 mis yn olynol neu gyfnod hwy i gleifion sydd wedi eu diagnosisio ag anableddau dysgu ynghyd ag i gleifion ag afiechyd meddwl; neu
  - (ii) am gyfnod o 12 mis yn olynol neu gyfnod hwy i glaf sydd wedi ei ddiagnosisio fel un sydd ag anabledd dysgu yn ogystal ag afiechyd meddwl,

gynnwys mwy na 15 o leoedd cymeradwy.

- (b) rhaid i'r person cofrestredig sicrhau na chaiff ysbyty annibynnol sy'n darparu, neu'n bwriadu darparu, llety dros nos i glaf sydd wedi ei ddiagnosisio ag anableddau dysgu nad yw'n dod

needed by employees in connection with their work, sleeping accommodation.

(4) Subject to paragraph 5 the registered person must—

- (a) take adequate precautions against the risk of fire, including the provision and maintenance of adequate fire prevention and detection equipment;
- (b) provide adequate means of escape in the event of a fire;
- (c) make arrangements for persons employed in the establishment and medical practitioners to whom practising privileges have been granted to receive suitable training in fire prevention;
- (d) ensure, by means of fire drills and practices at suitable intervals, that the persons employed in the establishment and, so far as practicable, patients and medical practitioners to whom practising privileges have been granted, are aware of the procedure to be followed in case of fire;
- (e) review fire precautions, the suitability of fire equipment and the procedure to be followed in case of fire at intervals not exceeding twelve months; and
- (f) produce a written fire safety risk assessment.

(5) Where the Regulatory Reform (Fire Safety) Order 2005(1) applies to the premises—

- (a) paragraph (4) does not apply; and
- (b) the registered person must ensure that the requirements of that Order and any regulations made under it, except for article 23 (duties of employees), are complied with in respect of those premises.

### **Fitness of premises – learning disability**

27.—(1) Subject to regulation 53—

- (a) the registered person must ensure that an independent hospital that provides, or intends to provide, overnight accommodation—
  - (i) for a consecutive period of 12 months or more for patients diagnosed with a learning disability together with patients with a mental illness; or
  - (ii) for a consecutive period of 12 months or more to a patient diagnosed with both a learning disability and mental illness,

must not exceed 15 approved places.

- (b) the registered person must ensure that an independent hospital that provides, or intends to provide, overnight accommodation to a patient diagnosed with learning disabilities

(1) O.S. 2005/1541.

(1) S.I. 2005/1541.

o fewn is-baragraff (1)(a), am 12 mis yn olynol neu fwy, gynnwys mwy na 10 lle cymeradwy.

- (c) rhaid i'r person cofrestredig sicrhau, pan fo'n rhesymol ymarferol, y darperir y lleoedd cymeradwy y cyfeirir atynt ym mharagraff (1) mewn dwy neu ragor o unedau o'r ysbyty annibynnol.

Pennod 3  
Rheolaeth

### Ymweliadau gan y darparwr cofrestredig â sefydliadau

28.–(1) Os yw'r darparwr cofrestredig yn unigolyn, nad yw'n rheoli'r sefydliad, rhaid i'r unigolyn hwnnw ymweld â mangre'r sefydliad yn unol â'r rheoliad hwn.

(2) Os yw'r darparwr cofrestredig yn gorff, rhaid i un o'r canlynol ymweld â'r sefydliad yn unol â'r rheoliad hwn–

- (a) yr unigolyn cyfrifol;
- (b) un arall o'r cyfarwyddwyr neu'r personau eraill sy'n gyfrifol am reoli'r corff ac sy'n addas i ymweld â'r sefydliad; neu
- (c) un o gyflogeion y corff a chanddo gymwysterau, sgiliau a phrofiad priodol at y diben hwnnw ac nad yw'n ymwneud yn uniongyrchol â rhedeg y sefydliad.

(3) Rhaid gwneud yr ymweliadau o dan baragraff (1) neu (2) o leiaf unwaith bob chwe mis, a cheir eu gwneud yn ddirybudd.

(4) Rhaid i'r person sy'n ymgymryd ag ymweliad–

- (a) cyfweld, gyda'u cydsyniad ac yn breifat (ar y teleffon, os oes angen), y cyfryw rai o'r cleifion a chynrychiolwyr y cleifion a'r cyfryw gyflogeion yr ymddengys yn angenrheidiol er mwyn ffurfio barn am safon y driniaeth a'r gwasanaethau eraill a ddarperir yn y sefydliad neu at ddibenion y sefydliad;
- (b) archwilio'r fangre a chofnodion o unrhyw gwynion; ac
- (c) paratoi adroddiad ysgrifenedig ar y modd y mae'r sefydliad yn cael ei redeg.

(5) Rhaid i'r darparwr cofrestredig ddarparu copi o'r adroddiad y mae'n ofynnol ei baratoi o dan baragraff (4)(c) i–

- (a) yr awdurdod cofrestru;
- (b) y rheolwr cofrestredig; ac
- (c) yn achos ymweliad o dan baragraff (2), i bob un o'r cyfarwyddwyr neu'r personau eraill sy'n gyfrifol am reoli'r corff.

who does not fall within sub-paragraph (1)(a), for a consecutive period of 12 months or more, must not exceed 10 approved places.

(2) The registered person must ensure that, where reasonably practicable, the approved places referred to in paragraph (1) are provided in two or more units of the independent hospital.

Chapter 3  
Management

### Visits by registered provider to establishments

28.–(1) Where the registered provider is an individual who does not manage the establishment, that individual must visit the establishment premises in accordance with this regulation.

(2) Where the registered provider is an organisation, the establishment must be visited in accordance with this regulation by–

- (a) the responsible individual;
- (b) another of the directors or other persons responsible for the management of the organisation who is suitable to visit the establishment; or
- (c) an employee of the organisation who has appropriate qualifications, skills and experience for the purpose and who is not directly concerned with the conduct of the establishment.

(3) Visits under paragraph (1) or (2) must take place at least every six months and may be unannounced.

(4) The person carrying out the visit must–

- (a) interview, with their consent and in private (if necessary, by telephone), such of the patients and their representatives and such employees as appear to be necessary in order to form an opinion of the standard of treatment and other services provided in or for the purposes of the establishment;
- (b) inspect the premises and records of any complaints; and
- (c) prepare a written report on the conduct of the establishment.

(5) The registered provider must supply a copy of the report required to be made under paragraph (4)(c) to–

- (a) the registration authority;
- (b) the registered manager; and
- (c) in the case of a visit under paragraph (2), to each of the directors or other persons responsible for the management of the organisation.

## Sefyllfa ariannol

29.–(1) Rhaid i'r darparwr cofrestredig redeg y sefydliad neu'r asiantaeth mewn modd sy'n debyg o sicrhau y bydd y sefydliad neu'r asiantaeth yn hyfyw yn ariannol at y diben o gyrraedd y nodau a'r amcanion a bennir yn y datganiad o ddiben.

(2) Rhaid i'r person cofrestredig, os gofynnir iddo gan yr awdurdod cofrestru, ddarparu pa bynnag wybodaeth a dogfennau i'r awdurdod cofrestru ag a fydd yn ofynnol gan yr awdurdod cofrestru at y diben o ystyried hyfywedd ariannol y sefydliad neu'r asiantaeth, gan gynnwys–

- (a) cyfrifon blynyddol yr awdurdod neu'r asiantaeth, a ardystiwyd gan gyfrifydd; neu
- (b) cyfrifon blynyddol y corff sy'n ddarparwr cofrestredig y sefydliad neu'r asiantaeth, wedi eu hardystio gan gyfrifydd, ynghyd â chyfrifon mewn perthynas â'r sefydliad neu'r asiantaeth ei hunan.

(3) Rhaid i'r person cofrestredig ddarparu hefyd i'r awdurdod cofrestru ba bynnag wybodaeth arall a fydd yn ofynnol gan yr awdurdod cofrestru er mwyn ystyried hyfywedd ariannol y sefydliad neu'r asiantaeth, gan gynnwys–

- (a) tystlythyr gan fanc yn mynegi barn ynghylch statws ariannol y darparwr cofrestredig;
- (b) gwybodaeth am y modd yr ariennir y sefydliad neu'r asiantaeth ac am ei adnoddau ariannol, neu ei hadnoddau ariannol;
- (c) os yw'r darparwr cofrestredig yn gwmni, gwybodaeth am unrhyw rai o'i gwmnïau cysylltiedig; ac
- (ch) tystysgrif yswiriant ar gyfer y darparwr cofrestredig mewn perthynas ag atebolrwydd y gellid ei achosi iddo mewn perthynas â'r sefydliad neu'r asiantaeth ynglŷn â marwolaeth, anaf, atebolrwydd cyhoeddus, difrod neu golled arall.

(4) Yn y rheoliad hwn, mae un cwmni yn gysylltiedig â chwmni arall os rheolir un ohonynt gan y llall, neu os yw'r ddau o dan reolaeth yr un person.

### Pennod 4

Hysbysiadau sydd i'w rhoi i'r awdurdod cofrestru

## Hysbysu am farwolaeth neu absenoldeb diawdurdod claf a gedwir yn gaeth neu sy'n agored i'w gaethiwo o dan Ddeddf Iechyd Meddwl 1983

30.–(1) Rhaid i'r person cofrestredig hysbysu'r awdurdod cofrestru yn ddi-oed ynghylch marwolaeth neu absenoldeb diawdurdod claf sy'n agored i'w gaethiwo gan y person cofrestredig–

- (a) o dan Ddeddf Iechyd Meddwl 1983 ("Deddf

## Financial position

29.–(1) The registered provider must carry on the establishment or agency in such manner as is likely to ensure that the establishment or agency will be financially viable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person must, if the registration authority so requests, provide it with such information and documents as it may require for the purpose of considering the financial viability of the establishment or agency, including–

- (a) the annual accounts of the establishment or agency, certified by an accountant; or
- (b) the annual accounts of the organisation which is the registered provider of the establishment or agency, certified by an accountant, together with accounts relating to the establishment or agency itself.

(3) The registered person must also provide the registration authority with such other information as it may require in order to consider the financial viability of the establishment or agency, including–

- (a) a reference from a bank expressing an opinion as to the registered provider's financial standing;
- (b) information as to the financing and financial resources of the establishment or agency;
- (c) where the registered provider is a company, information as to any of its associated companies; and
- (d) a certificate of insurance for the registered provider in respect of liability which may be incurred by the provider in relation to the establishment or agency in respect of death, injury, public liability, damage or other loss.

(4) In this regulation, one company is associated with another if one of them has control of the other, or both are under the control of the same person.

### Chapter 4

Notices to be given to the registration authority

## Notification of death or unauthorised absence of a patient who is detained or liable to be detained under the Mental Health Act 1983

30.–(1) The registered person must notify the registration authority without delay of the death or unauthorised absence of a patient who is liable to be detained by the registered person–

- (a) under the Mental Health Act 1983 ("the 1983



1983"); neu

- (b) yn unol â gorchymyn neu gyfarwyddyd a wneir o dan ddeddfiad arall (sy'n gymwys o ran Cymru), a'r caethiwo hwnnw'n cael effaith fel pe bai'r gorchymyn neu'r cyfarwyddyd wedi ei wneud yn unol â darpariaethau Deddf 1983.

(2) Yn y rheoliad hwn—

- (a) mae cyfeiriadau at bersonau sy'n "agored i'w caethiwo" ("*liable to be detained*") yn cynnwys claf cymunedol a adalwyd i ysbyty yn unol ag adran 17E o Ddeddf 1983, ond nid ydynt yn cynnwys claf a ryddhawyd yn amodol ac nas adalwyd i ysbyty yn unol ag adran 42, 73 neu 74 o Ddeddf 1983;
- (b) mae i "claf cymunedol" yr ystyr a roddir i "*community patient*" yn adran 17A o Ddeddf 1983;
- (c) mae i "ysbyty" yr ystyr a roddir i "*hospital*" yn Rhan 2 o'r Ddeddf honno; ac
- (ch) ystyr "absenoldeb diawdurdod" ("*unauthorised absence*") yw absenoldeb diawdurdod o ysbyty.

### Hysbysu am ddigwyddiadau

31.—(1) Rhaid i'r person cofrestredig hysbysu swyddfa briodol yr awdurdod cofrestru—

- (a) am farwolaeth claf—
  - (i) mewn sefydliad;
  - (ii) yn ystod triniaeth a ddarparwyd mewn neu at ddibenion sefydliad neu at ddibenion asiantaeth; neu
  - (iii) o ganlyniad i driniaeth a ddarparwyd mewn neu at ddibenion sefydliad neu at ddibenion asiantaeth;

ac am ddyddiad, amser, achos (os yw'n hysbys) ac amgylchiadau marwolaeth y claf;

- (b) am unrhyw anaf difrifol i glaf;
- (c) am achos sy'n digwydd mewn sefydliad o unrhyw glefyd heintus sydd, ym marn unrhyw ymarferydd meddygol a gyflogir yn y sefydliad, yn ddigon difrifol i roi hysbysiad yn ei gylch;
- (ch) unrhyw honiad o gamymddwyn sy'n arwain at niwed gwirioneddol neu niwed posibl i glaf, gan y person cofrestredig, unrhyw berson a gyflogir yn, neu at ddibenion, y sefydliad neu at ddibenion yr asiantaeth, neu unrhyw ymarferydd meddygol sydd â breintiau ymarfer;
- (d) unrhyw gais am awdurdodiad safonol a wneir gan y person cofrestredig i gorff goruchwyllo yn unol â Rhan 4 o Atodlen A1 i Ddeddf 2005, gan gynnwys canlyniad cais o'r fath;

Act"); or

- (b) pursuant to an order or direction made under another enactment (which applies in relation to Wales), where that detention takes effect as if the order or direction were made pursuant to the provisions of the 1983 Act.

(2) In this regulation—

- (a) References to persons "liable to be detained" ("*agored i'w caethiwo*") include a community patient who has been recalled to hospital in accordance with section 17E of the 1983 Act, but do not include a patient who has been conditionally discharged and not recalled to hospital in accordance with section 42, 73 or 74 of the 1983 Act;
- (b) "community patient" ("*claf cymunedol*") has the same meaning as in section 17A of the 1983 Act;
- (c) "hospital" ("*ysbyty*") means a hospital within the meaning of Part 2 of that Act; and
- (d) "unauthorised absence" ("*absenoldeb diawdurdod*") means an unauthorised absence from a hospital.

### Notification of events

31.—(1) The registered person must give notice to the appropriate office of the registration authority of—

- (a) the death of a patient—
  - (i) in an establishment;
  - (ii) during treatment provided in or for the purposes of an establishment or for the purposes of an agency; or
  - (iii) as a consequence of treatment provided in or for the purposes of an establishment or for the purposes of an agency;

and the date, time, cause (where known) and circumstances of the patient's death;

- (b) any serious injury to a patient;
- (c) the outbreak in an establishment of any infectious disease, which in the opinion of any medical practitioner employed in the establishment is sufficiently serious to be so notified;
- (d) any allegation of misconduct resulting in actual or potential harm to a patient by the registered person, any person employed in or for the purposes of the establishment or for the purposes of an agency, or any medical practitioner with practising privileges;
- (e) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act by the registered person for a standard authorisation, including the result of such a request;

(dd) unrhyw gais a wneir i lys ynglŷn ag amddifadu claf o'i ryddid.

(2) At ddibenion y rheoliad hwn, mae cyfeiriadau at gorff goruchwyllo yn gyfeiriadau at "*supervisory body*" fel y'i diffinnir yn Atodlen A1 i Ddeddf 2005(1) ac mae i "awdurdodiad safonol" yr ystyr a roddir i "*standard authorisation*" yn Rhan 4 o Atodlen A1 i Ddeddf 2005.

(3) Rhaid rhoi'r hysbysiad o dan baragraff (1) o fewn y cyfnod o 24 awr sy'n dechrau gyda'r digwyddiad dan sylw ac, os rhoddir hysbysiad ar lafar, rhaid ei gadarnhau mewn ysgrifen o fewn 72 awr ar ôl yr hysbysiad llafar.

(4) Os—

- (a) yw'r person cofrestredig yn cael gwybodaeth am farwolaeth claf y terfynwyd ei beichiogrwydd mewn ysbyty annibynnol yn ystod y cyfnod o 12 mis a ddaw i ben ar y dyddiad y ceir yr wybodaeth; a
- (b) os oes rheswm gan y person cofrestredig i gredu y gallai fod marwolaeth y claf yn gysylltiedig â therfynu'r beichiogrwydd, rhaid i'r person cofrestredig hysbysu swyddfa briodol yr awdurdod cofrestru mewn ysgrifen o fewn y cyfnod o 14 diwrnod sy'n dechrau ar y diwrnod y ceir yr wybodaeth.

#### **Hysbysu ynghylch absenoldeb person cofrestredig**

32.—(1) Os yw—

- (a) darparwr; cofrestredig sy'n rheoli'r sefydliad neu'r asiantaeth; neu
- (b) rheolwr cofrestredig,

yn bwriadu bod yn absennol o'r sefydliad neu asiantaeth am gyfnod di-dor o 28 diwrnod neu ragor, rhaid i'r person cofrestredig hysbysu swyddfa briodol yr awdurdod cofrestru mewn ysgrifen o'r absenoldeb.

(2) Ac eithrio mewn achos o argyfwng, rhaid i'r hysbysiad y cyfeirir ato ym mharagraff (1) gael ei roi ddim hwyrach nag un mis cyn dechrau'r absenoldeb arfaethedig, neu o fewn unrhyw gyfnod byrrach y cytunir arno gyda'r awdurdod cofrestru a rhaid i'r hysbysiad nodi, mewn perthynas â'r absenoldeb—

- (a) ei hyd neu'i hyd disgwylidig;
- (b) y rheswm drosto;
- (c) y trefniadau sydd wedi'u gwneud ar gyfer rhedeg y sefydliad neu'r asiantaeth;
- (ch) enw, cyfeiriad a chymwysterau'r person a fydd yn gyfrifol am y sefydliad neu'r asiantaeth yn ystod yr absenoldeb hwnnw; a
- (d) y trefniadau sydd wedi, neu y bwriedir, eu gwneud ar gyfer penodi person arall i reoli'r

(f) any application made to a court in relation to depriving a patient of their liberty.

(2) For the purposes of this regulation, references to a supervisory body are to a supervisory body as defined in Schedule A1 to the 2005 Act(1) and "standard authorisation" ("*awdurdodiad safonol*") has the meaning given under Part 4 of Schedule A1 to the 2005 Act.

(3) Notice under paragraph (1) must be given within the period of 24 hours beginning with the event in question and, if given orally, must be confirmed in writing within 72 hours of the oral notification.

(4) If the registered person—

- (a) receives information concerning the death of a patient who has undergone termination of a pregnancy in an independent hospital during the period of 12 months ending on the date on which the information is received; and
- (b) has reason to believe that the patient's death may be associated with the termination, the registered person must give notice in writing to the appropriate office of the registration authority of that information, within the period of 14 days beginning on the day on which the information is received.

#### **Notice of absence of registered person**

32.—(1) Where—

- (a) a registered provider who manages the establishment or agency; or
- (b) a registered manager,

proposes to be absent from the establishment or agency for a continuous period of 28 days or more, the registered person must give notice in writing to the appropriate office of the registration authority of the absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than one month before the proposed absence commences or within such shorter period as may be agreed with the registration authority and the notice must specify with respect to the absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for running the establishment or agency;
- (d) the name, address and qualifications of the person who will be responsible for the establishment or agency during that absence; and
- (e) the arrangements that have been or are proposed to be made for appointing another

(1) *Gweler* Atodlen A1, rhan 13.

(1) *See* Schedule A1, part 13.

sefydliad neu'r asiantaeth yn ystod yr absenoldeb hwnnw, gan gynnwys pa ddyddiad y bwriedir gwneud y penodiad hwnnw.

(3) Os yw'r absenoldeb yn codi o ganlyniad i argyfwng, rhaid i'r person cofrestredig roi hysbysiad o'r absenoldeb o fewn un wythnos wedi i'r argyfwng ddigwydd, gan nodi'r materion a bennir yn is-baragraffau (a) i (d) o baragraff (2).

(4) Os yw—

- (a) darparwr cofrestredig sy'n rheoli'r sefydliad neu'r asiantaeth; neu
- (b) rheolwr cofrestredig,

wedi bod yn absennol o'r sefydliad neu'r asiantaeth am gyfnod di-dor o 28 diwrnod neu ragor, ac os na hysbyswyd swyddfa briodol yr awdurdod cofrestru o'r absenoldeb rhaid i'r person cofrestredig roi hysbysiad ysgrifenedig yn ddi-od i'r swyddfa honno gan nodi'r materion a bennir yn is-baragraffau (a) i (d) o baragraff (2).

(5) Rhaid i'r person cofrestredig hysbysu swyddfa briodol yr awdurdod cofrestru o ddychweliad person a grybwyllir yn is-baragraff (a) neu (b) o baragraff (4) i'w waith, ddim hwyrach na 7 diwrnod ar ôl dyddiad dychweliad y person hwnnw.

### Hysbysu ynghylch newidiadau

**33.**—(1) Rhaid i'r person cofrestredig hysbysu swyddfa briodol yr awdurdod cofrestru mewn ysgrifenedig cyn gynted ag y bo'n ymarferol, os digwydd unrhyw un o'r digwyddiadau canlynol neu os bwriedir i unrhyw un ohonynt ddigwydd—

- (a) person ac eithrio'r person cofrestredig yn rhedeg neu'n rheoli'r sefydliad neu'r asiantaeth;
- (b) person yn peidio â rhedeg neu reoli'r sefydliad neu'r asiantaeth;
- (c) pan fo'r person cofrestredig yn unigolyn, yr unigolyn hwnnw yn newid ei enw;
- (ch) pan fo'r darparwr cofrestredig yn gorff—
  - (i) newid enw neu gyfeiriad y corff;
  - (ii) newid cyfarwyddwr, rheolwr, ysgrifennydd neu swyddog cyffelyb arall y corff;
- (d) yr unigolyn cyfrifol yn newid ei enw;
- (dd) enwi rhywun arall yn unigolyn cyfrifol;
- (e) pan fo'r darparwr cofrestredig yn unigolyn, penodi ymddiriedolwr mewn methodaliad, neu wneud compôwnd neu drefniant gyda chredydwy;
- (f) pan fo'r darparwr cofrestredig yn gwmni neu'n

person to manage the establishment or agency during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence arises as a result of an emergency, the registered person must give notice of the absence within one week of the emergency's occurrence specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(4) Where—

- (a) a registered provider who manages the establishment or agency; or
- (b) a registered manager,

has been absent from the establishment or agency for a continuous period of 28 days or more, and the appropriate office of the registration authority has not been given notice of the absence, the registered person must, without delay, give notice in writing to that office, specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(5) The registered person must notify the appropriate office of the registration authority of the return to work of a person mentioned in sub-paragraph (a) or (b) of paragraph (4) not later than 7 days after the date of that person's return.

### Notice of changes

**33.**—(1) The registered person must give notice in writing to the appropriate office of the registration authority as soon as it is practicable to do so if any of the following events take place or are proposed to take place—

- (a) a person other than the registered person carries on or manages the establishment or agency;
- (b) a person ceases to carry on or manage the establishment or agency;
- (c) where the registered person is an individual, he or she changes his or her name;
- (d) where the registered provider is an organisation—
  - (i) the name or address of the organisation is changed;
  - (ii) there is any change of director, manager, secretary or other similar officer of the organisation;
- (e) the responsible individual changes his or her name;
- (f) there is any change in the identity of the responsible individual;
- (g) where the registered provider is an individual, a trustee in bankruptcy is appointed or a composition or arrangement is made with creditors;
- (h) where the registered provider is a company or

bartneriaeth, penodi derbynnydd, rheolwr, datodwr neu ddatodwr dros dro; neu

- (ff) newid neu ehangu mangre'r sefydliad yn sylweddol, neu gaffael mangre ychwanegol, y bwriedir ei defnyddio at ddibenion y sefydliad.

### **Penodi datodwyr etc**

**34.**–(1) Rhaid i unrhyw berson y mae paragraff (2) yn gymwys iddo–

- (a) hysbysu swyddfa briodol yr awdurdod cofrestru ar unwaith o benodiad y person, gan nodi'r rhesymau dros ei benodi;
- (b) penodi rheolwr i gymryd gofal amser–llawn o ddydd i ddydd o'r sefydliad neu'r asiantaeth mewn unrhyw achos pan nad yw'r ddyletswydd o dan reoliad 11(1) yn cael ei chyflawni; ac
- (c) cyn diwedd y cyfnod o 28 diwrnod sy'n dechrau ar y dyddiad y penodir y person, hysbysu swyddfa briodol yr awdurdod cofrestru o fwriadau'r person ynglŷn â pharhau yn y dyfodol i weithredu'r sefydliad neu'r asiantaeth y'i penodwyd mewn perthynas ag ef neu hi.

(2) Mae'r paragraff hwn yn gymwys i unrhyw berson a benodwyd–

- (a) yn dderbynnydd neu'n rheolwr eiddo corff sy'n ddarparwr cofrestredig sefydliad neu asiantaeth;
- (b) yn ddatodwr neu'n ddatodwr dros dro cwmni sy'n ddarparwr cofrestredig sefydliad neu asiantaeth;
- (c) yn ymddiriedolwr mewn methdaliad i ddarparwr cofrestredig sefydliad neu asiantaeth.

### **Marwolaeth person cofrestredig**

**35.**–(1) Os oes mwy nag un person wedi'i gofrestru mewn perthynas â sefydliad neu asiantaeth ac os bydd farw person cofrestredig, rhaid i'r person cofrestredig sy'n goroesi hysbysu swyddfa briodol yr awdurdod cofrestru o'r farwolaeth, mewn ysgrifen yn ddi-oed.

(2) Os nad oes ond un person wedi'i gofrestru mewn perthynas â sefydliad neu asiantaeth, ac os bydd farw'r person hwnnw, rhaid i gynrychiolwyr personol y person hysbysu swyddfa briodol yr awdurdod cofrestru mewn ysgrifen–

- (a) o'r farwolaeth yn ddi-oed; a
- (b) o fewn 28 diwrnod, o'u bwriadau ynglŷn â rhedeg y sefydliad neu'r asiantaeth yn y dyfodol.

(3) Caiff cynrychiolwyr personol darparwr cofrestredig a fu farw redeg y sefydliad neu'r asiantaeth

partnership, a receiver, manager, liquidator or provisional liquidator is appointed; or

- (i) the premises of the establishment are significantly altered or extended, or additional premises are acquired which are intended to be used for the purposes of the establishment.

### **Appointment of liquidators etc**

**34.**–(1) Any person to whom paragraph (2) applies must–

- (a) forthwith notify the appropriate office of the registration authority of the person's appointment indicating the reasons for it;
- (b) appoint a manager to take full-time day to day charge of the establishment or agency in any case where the duty under regulation 11(1) is not being met; and
- (c) before the end of the period of 28 days beginning on the date of the person's appointment, notify the appropriate office of the registration authority of the person's intentions regarding the future operation of the establishment or agency to which the appointment relates.

(2) This paragraph applies to any person appointed as–

- (a) the receiver or manager of the property of an organisation which is a registered provider of an establishment or agency;
- (b) a liquidator or provisional liquidator of a company which is the registered provider of an establishment or agency;
- (c) the trustee in bankruptcy of a registered provider of an establishment or agency.

### **Death of registered person**

**35.**–(1) If more than one person is registered in respect of an establishment or agency, and a registered person dies, the surviving registered person must without delay notify the appropriate office of the registration authority of the death in writing.

(2) If only one person is registered in respect of an establishment or agency, and the person dies, the person's personal representatives must notify the appropriate office of the registration authority in writing–

- (a) without delay of the death; and
- (b) within 28 days of their intentions regarding the future running of the establishment or agency.

(3) The personal representatives of the deceased registered provider may carry on the establishment or

heb gael eu cofrestru mewn perthynas â'r sefydliad neu'r asiantaeth—

- (a) am gyfnod na fydd yn hwy nag 28 diwrnod; a
- (b) am unrhyw gyfnod pellach y caiff yr awdurdod cofrestru ei benderfynu yn unol â pharagraff (4).

(4) Caiff yr awdurdod cofrestru estyn y cyfnod a bennir ym mharagraff (3)(a) am ba bynnag gyfnod pellach, na fydd yn hwy na 6 mis, a benderfynir gan yr awdurdod cofrestru, a rhaid i'r awdurdod cofrestru hysbysu'r cynrychiolwyr personol o unrhyw benderfyniad o'r fath, mewn ysgrifen.

(5) Rhaid i'r cynrychiolwyr personol benodi rheolwr i gymryd gofal amser-llawn o'r sefydliad neu'r asiantaeth o ddydd i ddydd yn ystod unrhyw gyfnod pan fyddant yn rhedeg y sefydliad neu'r asiantaeth yn unol â pharagraff (3), a hwythau heb eu cofrestru mewn perthynas â'r sefydliad neu'r asiantaeth.

(6) Mae darpariaethau rheoliad 12 yn gymwys i reolwr a benodir yn unol â pharagraff (5).

agency without being registered in respect of it—

- (a) for a period not exceeding 28 days; and
- (b) for any further period as may be determined by the registration authority in accordance with paragraph (4).

(4) The registration authority may extend the period specified in paragraph (3)(a) by such further period, not exceeding 6 months, as the registration authority may determine, and must notify any such determination to the personal representatives in writing.

(5) The personal representatives must appoint a manager to take full-time day to day charge of the establishment or agency during any period in which, in accordance with paragraph (3), they carry on the establishment or agency without being registered in respect of it.

(6) The provisions of regulation 12 apply to a manager appointed in accordance with paragraph (5).

#### **RHAN IV**

Gofynion Ychwanegol sy'n Gymwys i Ysbytai Annibynnol

Pennod 1

Gwasanaethau Patholeg, Dadebru a Thrin Plant mewn Ysbytai Annibynnol

#### **Cymhwyso rheoliadau 37 i 39**

**36.—(1)** Mae rheoliadau 37 i 39 yn gymwys i ysbytai annibynnol o'r mathau canlynol—

- (a) y rhai a ddiffinnir yn adran 2(3)(a)(i) o'r Ddeddf ac eithrio sefydliadau sydd wedi'u heithrio gan reoliad 3(3); a
- (b) y rhai lle mae triniaeth feddygol, gan gynnwys llawdriniaeth gosmetig, yn cael ei darparu o dan anaesthesia neu dawelydd.

(2) Mae rheoliad 37 yn gymwys hefyd i unrhyw sefydliad sy'n darparu gwasanaethau patholeg.

#### **Gwasanaethau patholeg**

**37.** Rhaid i'r person cofrestredig sicrhau—

- (a) bod ystod ddigonol o wasanaethau patholeg ar gael i fodloni anghenion yr ysbyty;
- (b) y darperir y gwasanaethau hynny yn unol â safon briodol;
- (c) y gwneir trefniadau priodol ar gyfer casglu sbesimenau patholeg, ac ar gyfer eu cludo (os darperir gwasanaethau patholeg y tu allan i'r ysbyty); ac

#### **PART IV**

Additional Requirements applying to Independent Hospitals

Chapter 1

Pathology Services, Resuscitation and Treatment of Children in Independent Hospitals

#### **Application of regulations 37 to 39**

**36.—(1)** Regulations 37 to 39 apply to independent hospitals of the following kinds—

- (a) those defined in section 2(3)(a)(i) of the Act except establishments excepted by regulation 3(3); and
- (b) those in which medical treatment, including cosmetic surgery, is provided under anaesthesia or sedation.

(2) Regulation 37 also applies to any establishment which provides pathology services.

#### **Pathology services**

**37.** The registered person must ensure that—

- (a) an adequate range of pathology services is available to meet the needs of the hospital;
- (b) those services are provided to an appropriate standard;
- (c) appropriate arrangements are made for the collection, and (where pathology services are provided outside the hospital) transportation of pathology specimens; and

- (ch) bod modd bob amser adnabod y person y cymerwyd sbesimen ohono, ac adnabod y sbesimen.

### Dadebru

38.–(1) Rhaid i'r person cofrestredig baratoi a rhoi ar waith ddatganiad ysgrifenedig o'r polisïau sydd i'w cymhwyso a'r gweithdrefnau sydd i'w dilyn yn yr ysbyty mewn perthynas â dadebru cleifion a rhaid iddo adolygu'r datganiad hwnnw bob blwyddyn.

(2) Rhaid i'r person cofrestredig sicrhau bod y polisïau a'r gweithdrefnau a roddir ar waith yn unol â pharagraff (1)–

- (a) yn rhoi ystyriaeth briodol i hawl pob claf sydd â'r galluedd i wneud hynny i roi neu wrthod rhoi cydsyniad i driniaeth;
- (b) yn rhoi ystyriaeth briodol i benderfyniadau dilys a chymwys a wneir ymlaen llaw gan gleifion o dan Ddeddf 2005;
- (c) ar gael, os gofynnir am eu gweld, i bob claf ac i unrhyw berson sy'n gweithredu ar ran claf; ac
- (ch) yn cael eu cyfathrebu i, a'u deall gan, bob cyflogai a phob ymarferydd meddygol â breintiau ymarfer a allai fod yn gysylltiedig â phenderfyniadau ynghylch dadebru claf.

### Trin plant

39. Rhaid i'r person cofrestredig sicrhau, pan fo plentyn yn cael ei drin yn yr ysbyty–

- (a) y trinnir y plentyn mewn llety ar wahân i'r llety y trinnir cleifion sy'n oedolion ynddo;
- (b) y bodlonir yr anghenion meddygol, corfforol, seicolegol, cymdeithasol ac addysgol penodol a'r anghenion penodol o ran goruchwyllo sy'n deillio o oedran y plentyn;
- (c) y darperir y driniaeth i'r plentyn gan bersonau sydd â chymwysterau, sgiliau a phrofiad priodol ar gyfer trin plant;
- (ch) yr hysbysir rhieni'r plentyn yn llawn ynghylch cyflwr y plentyn ac, i'r graddau y bo'n ymarferol, yr ymgynghorir â hwy ynglŷn â phob agwedd ar y driniaeth a roddir i'r plentyn, ac eithrio pan fo'r plentyn ei hunan yn gymwys i roi cydsyniad i driniaeth ac nad yw'n dymuno i neb hysbysu nac ymgynghori â'i rieni felly.

#### Pennod 2

Ysbytai Annibynnol Lle y Darperir Gwasanaethau Rhestredig Penodol

### Gweithdrefnau llawfeddygol

40.–(1) Pan ddarperir triniaeth feddygol (gan gynnwys llawdriniaeth gosmetig) o dan anaesthesia neu

- (d) the patient from whom a specimen was taken, and such specimen, is identifiable at all times.

### Resuscitation

38.–(1) The registered person must prepare and implement a written statement of the policies to be applied and the procedures to be followed in the hospital in relation to resuscitation of patients and must review such statement annually.

(2) The registered person must ensure that the policies and procedures implemented in accordance with paragraph (1)–

- (a) take proper account of the right of all patients who have capacity to do so to give or withhold consent to treatment;
- (b) take proper account of valid and applicable advance decisions made by patients under the 2005 Act;
- (c) are available on request to every patient and any person acting on behalf of a patient; and
- (d) are communicated to and understood by all employees and all medical practitioners with practising privileges who may be involved in decisions about resuscitation of a patient.

### Treatment of children

39. The registered person must ensure that, where a child is treated in the hospital–

- (a) the child is treated in accommodation which is separate from accommodation in which adult patients are treated;
- (b) particular medical, physical, psychological, social, educational and supervision needs arising from the child's age are met;
- (c) the child's treatment is provided by persons who have appropriate qualifications, skills and experience in the treatment of children;
- (d) the child's parents are kept fully informed of the child's condition and so far as is practicable consulted about all aspects of the child's treatment, except where the child is competent to consent to treatment and does not wish his or her parents to be so informed and consulted.

#### Chapter 2

Independent Hospitals in which Certain Listed Services are Provided

### Surgical procedures

40.–(1) Where medical treatment (including cosmetic surgery) is provided under anaesthesia or

dawelydd mewn ysbyty annibynnol, rhaid i'r person cofrestredig sicrhau–

- (a) bod pob theatr llawdriniaethau wedi ei chynllunio, ei chyfarparu a'i chynnal hyd at safon sy'n briodol i'r dibenion y bwriedir ei defnyddio ar eu cyfer;
- (b) y cyflawnir pob llawdriniaeth gan, neu o dan gyfarwyddyd, ymarferydd meddygol sydd â chymwysterau, sgiliau a phrofiad addas;
- (c) bod nifer priodol o gyflogeion sydd â chymwysterau, sgiliau a phrofiad addas yn bresennol yn ystod pob gweithdrefn llawdriniaethol; ac
- (ch) bod y claf yn cael triniaeth briodol–
  - (i) cyn rhoi'r anesthetig neu'r tawelydd;
  - (ii) tra'n cael y weithdrefn lawfeddygol;
  - (iii) tra'n ymadfer ar ôl anesthesia cyffredinol; a
  - (iv) yn y cyfnod wedi'r llawdriniaeth.

(2) Rhaid i'r person cofrestredig sicrhau, cyn bod claf sydd â'r galluedd i wneud hynny yn cydsynio i unrhyw llawdriniaeth a gynigir gan yr ysbyty annibynnol, bod y claf wedi cael gwybodaeth eglur a chynhwysfawr ynglŷn â'r weithdrefn ac unrhyw risgiau sy'n gysylltiedig â hi.

(3) Yn achos claf nad oes ganddo alluedd i gydsynio i llawdriniaeth, rhaid, os oes modd, darparu'r wybodaeth a grybwyllir ym mharagraff (2) i'w gynrychiolwyr.

(4) Yn achos claf nad oes ganddo alluedd i gydsynio i llawdriniaeth, rhaid i'r person cofrestredig roi sylw priodol i unrhyw benderfyniadau dilys a chymwys a wnaed ymlaen llaw gan y claf o dan Ddeddf 2005.

### **Triniaeth ddeintyddol o dan anesthesia cyffredinol**

41. Pan fo'r driniaeth a ddarperir mewn ysbyty annibynnol yn cynnwys triniaeth ddeintyddol o dan anesthesia cyffredinol, rhaid i'r person cofrestredig sicrhau–

- (a) bod cymwysterau, sgiliau a phrofiad addas gan y deintydd ac unrhyw gyflogeion sy'n ei gynorthwyo i ddelio ag unrhyw argyfwng a all ddigwydd yn ystod neu o ganlyniad i'r anesthesia cyffredinol neu'r driniaeth; a
- (b) bod cyfleusterau, cyffuriau a chyfarpar digonol ar gael i ddelio ag unrhyw argyfwng o'r fath.

### **Gwasanaethau obstetrig – staffio**

42.–(1) Mae'r rheoliad hwn a rheoliad 43 yn gymwys i ysbyty annibynnol lle darperir gwasanaethau obstetrig ac, mewn perthynas â geni plant, gwasanaethau meddygol.

sedation in an independent hospital, the registered person must ensure that–

- (a) each operating theatre is designed, equipped and maintained to an appropriate standard for the purposes for which it is to be used;
- (b) all surgery is carried out by, or under the direction of, a suitably qualified, skilled and experienced medical practitioner;
- (c) an appropriate number of suitably qualified, skilled and experienced employees are in attendance during each surgical procedure; and
- (d) the patient receives appropriate treatment–
  - (i) before administration of an anaesthetic or sedation;
  - (ii) whilst undergoing a surgical procedure;
  - (iii) during recovery from general anaesthesia; and
  - (iv) post-operatively.

(2) The registered person must ensure that before a patient who has capacity to do so consents to any surgery offered by the independent hospital, the patient has received clear and comprehensive information about the procedure and any risks associated with it.

(3) In the case of a patient who lacks the capacity to consent to surgery, the information mentioned in paragraph (2) must, wherever possible, be provided to the patient's representatives.

(4) In the case of a patient who lacks capacity to consent to surgery, the registered person must take proper account of any valid and applicable advance decisions made by the patient under the 2005 Act.

### **Dental treatment under general anaesthesia**

41. Where the treatment provided in an independent hospital includes dental treatment under general anaesthesia, the registered person must ensure that–

- (a) the dentist and any employees assisting him or her are suitably qualified, skilled and experienced to deal with any emergency which occurs during or as a result of the general anaesthesia or treatment; and
- (b) adequate facilities, drugs and equipment are available to deal with any such emergency.

### **Obstetric services staffing**

42.–(1) This regulation and regulation 43 apply to an independent hospital in which obstetric services and, in connection with childbirth, medical services, are provided.

(2) Rhaid i'r person cofrestredig benodi Pennaeth Gwasanaethau Bydwreigiaeth i fod yn gyfrifol am reoli'r ddarpariaeth o wasanaethau bydwreigiaeth yn yr ysbyty annibynnol, ac yn ogystal, ac eithrio mewn achosion lle y darperir y gwasanaethau obstetrig yn yr ysbyty gan fydwragedd yn bennaf, Pennaeth Gwasanaethau Obstetrig y cynhwysir ei enw yn y gofrestr feddygol arbenigol mewn perthynas ag arbenigedd mewn obstetreg, i fod yn gyfrifol am reoli'r ddarpariaeth o wasanaethau obstetrig.

(3) Rhaid i'r person cofrestredig sicrhau bod y proffesiynolyn gofal iechyd sy'n bennaf cyfrifol am ofalu am fenywod beichiog a chynorthwyo adeg geni plant yn fydwraig, yn ymarferydd cyffredinol sydd â chymwysterau priodol, neu'n ymarferydd meddygol y cynhwysir ei enw yn y gofrestr feddygol arbenigol mewn perthynas ag arbenigedd mewn obstetreg.

(4) Os darperir y gwasanaethau obstetrig mewn ysbyty annibynnol yn bennaf gan fydwragedd, rhaid i'r person cofrestredig sicrhau bod gwasanaethau ymarferydd meddygol sy'n gymwys i ddelio ag argyfyngau obstetrig ar gael bob amser.

(5) Rhaid i'r person cofrestredig sicrhau bod proffesiynolyn gofal iechyd sy'n gymwys i ymgymryd â dadebru baban newydd anedig ar gael yn yr ysbyty bob amser a bod sgiliau'r person hwnnw yn cael eu hadolygu'n rheolaidd ac, os oes angen, eu diweddarau.

#### **Gwasanaethau obstetrig – gofynion pellach**

**43.–(1)** Rhaid i'r person cofrestredig sicrhau–

- (a) y rhoddir gwybod am farwolaeth unrhyw glaf mewn ysbyty annibynnol, sy'n digwydd yn ystod, neu o ganlyniad i, feichiogrwydd neu eni plentyn; a
- (b) y rhoddir gwybod am unrhyw farw-enedigaeth neu farwolaeth plentyn newydd-anedig mewn ysbyty annibynnol,

i unrhyw berson sy'n cynnal ymchwiliad i farwolaethau o'r fath ar ran Gweinidogion Cymru.

(2) Rhaid i'r person cofrestredig sicrhau bod cyfleusterau ar gael o fewn yr ysbyty i ddarparu triniaeth ddigonol i gleifion yr oedd angen ymyrraeth lawfeddygol arnynt, neu y defnyddiwyd gefeiliau arnynt wrth eni eu plentyn, a sicrhau y gofelir am gleifion o'r fath gan fydwraig a chanddi brofiad priodol.

(3) Rhaid i'r person cofrestredig sicrhau bod trefniadau priodol yn bodoli ar gyfer trosglwyddo claf a'i phlentyn newydd-anedig, ar unwaith pan fo angen, i gyfleusterau gofal critigol o fewn yr ysbyty neu mewn man arall yn y cyffiniau agos.

(4) Rhaid i'r person cofrestredig sicrhau bod trefniadau priodol yn bodoli ar gyfer trin, ac, os oes angen, trosglwyddo claf sy'n sâl iawn neu blentyn newydd-anedig i gyfleuster gofal arbenigol.

(2) The registered person must appoint a Head of Midwifery Services who is responsible for managing the provision of midwifery services in the independent hospital and, except in cases where obstetric services are provided in the hospital primarily by midwives, a Head of Obstetric Services whose name is included in the specialist medical register in respect of a specialty in obstetrics and who is responsible for managing the provision of obstetric services.

(3) The registered person must ensure that the health care professional who is primarily responsible for caring for pregnant women and assisting at childbirth is a midwife, an appropriately qualified general practitioner, or a medical practitioner whose name is included in the specialist medical register in respect of a specialty in obstetrics.

(4) Where obstetric services are provided in an independent hospital primarily by midwives, the registered person must ensure that the services of a medical practitioner who is competent to deal with obstetric emergencies are available at all times.

(5) The registered person must ensure that a health care professional who is competent to undertake resuscitation of a new born baby is available in the hospital at all times and that that person's skills are regularly reviewed and, if necessary, updated.

#### **Obstetric services further requirements**

**43.–(1)** The registered person must ensure that–

- (a) any death of a patient in an independent hospital during, or as a result of, pregnancy or childbirth; and
- (b) any stillbirth or neonatal death in an independent hospital,

are reported to any person undertaking an enquiry into such deaths on behalf of Welsh Ministers.

(2) The registered person must ensure that facilities are available within the hospital to provide adequate treatment to patients who have undergone a delivery requiring surgical intervention or the use of forceps and that such patients are cared for by an appropriately experienced midwife.

(3) The registered person must ensure that appropriate arrangements are in place for the immediate transfer, where necessary, of a patient and her new born child to critical care facilities within the hospital or elsewhere in the near vicinity.

(4) The registered person must ensure that appropriate arrangements are in place for the treatment and, if necessary transfer to a specialist care facility, of a very sick patient or new born child.



(5) Rhaid i'r person cofrestredig sicrhau bod cofnod mamolaeth yn cael ei gynnal ar gyfer pob claf sy'n cael gwasanaethau obstetrig a phob plentyn a enir yn yr ysbyty, ac—

- (i) y cynhwysir ynddo'r manylion a bennir yn rheoliad 23(1)(a) ac yn Rhannau I a II o Atodlen 4; a
- (ii) y delir gafael ar y cofnod mamolaeth am gyfnod o ddim llai na 25 mlynedd sy'n dechrau ar ddyddiad y cofnod diwethaf; a bydd gofynion rheoliad 23(2) yn gymwys i'r cofnod hwnnw.

(6) Yn y rheoliad hwn—

mae i "marw-enedigaeth" yr ystyr a roddir i "stillbirth" yn Neddf Cofrestru Genedigaethau a Marwolaethau 1953(1);

ystyr "marwolaeth plentyn newydd-anedig" ("neonatal death") yw marwolaeth plentyn cyn diwedd y cyfnod o 28 diwrnod sy'n dechrau gyda dyddiad geni'r plentyn.

### Terfynu beichiogrwydd

44.—(1) Mae'r rheoliad hwn yn gymwys i ysbyty annibynnol lle y terfynir beichiogrwydd.

(2) Rhaid i'r person cofrestredig sicrhau na dderbynnir unrhyw glaf i ysbyty i derfynu beichiogrwydd, ac na fynnir ac na dderbynnir ffi oddi wrth glaf mewn perthynas â therfynu, oni dderbyniwyd dwy dystysgrif barn mewn perthynas â'r claf.

(3) Rhaid i'r person cofrestredig sicrhau bod y tystysgrifau barn sy'n ofynnol o dan baragraff (2) yn cael eu cynnwys gyda chofnod meddygol y claf, o fewn ystyr rheoliad 23.

(4) Rhaid i'r person cofrestredig sicrhau na therfynir unrhyw feichiogrwydd ar ôl 20fed wythnos y beichiogiad, oni bai—

- (a) bod y claf yn cael ei drin gan bersonau a chanddynt gymwysterau, sgiliau a phrofiad addas i derfynu beichiogrwydd yn hwyr; a
- (b) bod gweithdrefnau priodol wedi'u sefydlu i ddelio ag unrhyw argyfwng meddygol sy'n digwydd yn ystod y terfynu neu o ganlyniad iddo.

(5) Rhaid i'r person cofrestredig sicrhau na chaiff unrhyw feichiogrwydd ei derfynu ar ôl 24ain wythnos y beichiogiad.

(6) Rhaid i'r person cofrestredig sicrhau y cedwir cofrestr yn yr ysbyty o'r cleifion sy'n terfynu eu beichiogrwydd, ac—

- (i) bod y gofrestr honno ar wahân i'r gofrestr o gleifion sydd i'w chadw o dan baragraff 1 o

(5) The registered person must ensure that a maternity record is maintained for each patient receiving obstetric services and each child born in the hospital, which—

- (i) includes the details specified in regulation 23(1)(a) and in Parts I and II of Schedule 4; and
- (ii) is retained for a period of not less than 25 years beginning on the date of the last entry; and the requirements of regulation 23(2) will apply to that record.

(6) In this regulation—

"stillbirth" ("marw-enedigaeth") has the meaning given to it in the Births and Deaths Registration Act 1953(1);

"neonatal death" ("marwolaeth plentyn newydd-anedig") means the death of a child before the end of the period of 28 days beginning with the date of the child's birth.

### Termination of pregnancies

44.—(1) This regulation applies to an independent hospital in which termination of pregnancies takes place.

(2) The registered person must ensure that no patient is admitted to the hospital for termination of a pregnancy, and that no fee is demanded or accepted from a patient in respect of a termination, unless two certificates of opinion have been received in respect of the patient.

(3) The registered person must ensure that the certificates of opinion required by paragraph (2) are included with the patient's medical record, within the meaning of regulation 23.

(4) The registered person must ensure that no termination of a pregnancy is undertaken after the 20th week of gestation, unless—

- (a) the patient is treated by persons who are suitably qualified, skilled and experienced in the late termination of pregnancy; and
- (b) appropriate procedures are in place to deal with any medical emergency which occurs during or as a result of the termination.

(5) The registered person must ensure that no termination of a pregnancy is undertaken after the 24th week of gestation.

(6) The registered person must ensure that a register of patients undergoing termination of a pregnancy in the hospital is maintained, which is—

- (i) separate from the register of patients which is to be maintained under paragraph 1 of

(1) 1953 p.20.

(1) 1953 c.20.

Atodlen 3;

- (ii) y cwblheir y gofrestr mewn perthynas â phob claf ar yr adeg y cyflawnir y terfyniad; a
- (iii) y delir gafael ar y gofrestr am gyfnod o ddim llai na thair blynedd, sy'n cychwyn ar ddyddiad y cofnod olaf.

(7) Rhaid i'r person cofrestredig baratoi a gweithredu gweithdrefnau priodol yn yr ysbyty er mwyn sicrhau bod meinweoedd ffetysol yn cael eu trin â pharch.

(8) Yn y rheoliad hwn, ystyr "tystysgrif barn" ("*certificate of opinion*") yw tystysgrif sy'n ofynnol gan reoliadau a wnaed o dan adran 2(1) o Ddeddf Erthyly 1967(1).

### Defnyddio technegau neu dechnolegau penodol

**45.**–(1) Rhaid i'r person cofrestredig sicrhau na ddefnyddir unrhyw gynnyrch laser Dosbarth 3B neu Ddosbarth 4 (o fewn ystyr rheoliad 3(1)), na ffynhonnell golau dwys (o fewn ystyr y rheoliad hwnnw) mewn ysbyty annibynnol neu at ddibenion ysbyty o'r fath oni fydd yr ysbyty hwnnw wedi sefydlu protocol proffesiynol, a baratowyd gan ymarferydd meddygol neu ddeintydd hyfforddedig a phrofiadol o'r ddisgyblaeth berthnasol, y bwriedir darparu'r driniaeth yn unol ag ef, ac y darperir y driniaeth yn unol â'r protocol hwnnw.

(2) Rhaid i'r person cofrestredig gadw cofrestr yn y sefydliad o bob achlysur pan ddefnyddiwyd techneg neu dechnoleg y cyfeirir ati ym mharagraff (1), gan gynnwys yn y gofrestr–

- (a) enw'r claf y defnyddiwyd y dechneg neu'r dechnoleg mewn cysylltiad â'i driniaeth;
- (b) natur y dechneg neu'r dechnoleg dan sylw a'r dyddiad y'i defnyddiwyd;
- (c) enw'r person a'i defnyddiodd; ac
- (ch) os nad oedd y person a ddefnyddiodd y dechneg neu dechnoleg yn ymarferydd meddygol, deintydd neu berson cymwys arall, enw a chymwysterau perthnasol yr ymarferydd meddygol neu'r deintydd a baratôdd y protocol proffesiynol y cyfeirir ato ym mharagraff (1).

(3) Rhaid i'r person cofrestredig sicrhau na ddefnyddir cynnyrch laser o'r fath na ffynhonnell golau dwys o'r fath yn yr ysbyty annibynnol nac ei ddibenion, ac eithrio gan berson sydd wedi cael hyfforddiant priodol ac wedi dangos dealltwriaeth o'r canlynol–

- (a) y dull cywir o ddefnyddio'r cyfarpar dan sylw;
- (b) y risgiau sy'n gysylltiedig â defnyddio cynnyrch laser neu ffynhonnell golau dwys;
- (c) ei effeithiau biolegol ac amgylcheddol;

Schedule 3;

- (ii) completed in respect of each patient at the time the termination is undertaken; and
- (iii) retained for a period of not less than three years beginning on the date of the last entry.

(7) The registered person must prepare and implement appropriate procedures in the hospital to ensure that foetal tissue is treated with respect.

(8) In this regulation, "certificate of opinion" ("*tystysgrif barn*") means a certificate required by regulations made under section 2(1) of the Abortion Act 1967(1).

### Use of certain techniques or technology

**45.**–(1) The registered person must ensure that no Class 3B or Class 4 laser product (within the meaning of regulation 3(1)), or intense light source (within the meaning of that regulation) is used in or for the purposes of an independent hospital unless that hospital has in place a professional protocol drawn up by a trained and experienced medical practitioner or dentist from the relevant discipline in accordance with which treatment is to be provided, and that the treatment is provided in accordance with it.

(2) The registered person must maintain at the establishment a register of each occasion when a technique or technology referred to in paragraph (1) has been used which includes–

- (a) the name of the patient in connection with whose treatment the technique or technology was used;
- (b) the nature of the technique or technology in question and the date on which it was used;
- (c) the name of the person using it; and
- (d) where the person using the technique or technology is not a medical practitioner, dentist or other competent person, the name and relevant qualifications of the medical practitioner or dentist who compiled the professional protocol referred to in paragraph (1).

(3) The registered person must ensure that such a laser product or intense light source is used in or for the purposes of the independent hospital only by a person who has undertaken appropriate training and has demonstrated an understanding of–

- (a) the correct use of the equipment in question;
- (b) the risks associated with using a laser product or intense light source;
- (c) its biological and environmental effects;

(1) 1967 p.87.

(1) 1967 c.87.

- (ch) y rhagofalon sydd i'w cymryd cyn defnyddio ac wrth ddefnyddio cynnyrch laser neu ffynhonnell golau dwys; a
- (d) y camau sydd i'w cymryd os digwydd unrhyw ddamwain, argyfwng, neu ddigwyddiad andwyol arall.

### Pennod 3

#### Ysbytai Iechyd Meddwl

#### Cymhwysio rheoliadau 47 i 50

46. Mae rheoliadau 47 i 50 yn gymwys i ysbytai annibynnol o'r mathau canlynol—

- (a) y rhai y mae darparu triniaeth feddygol neu seiciatrig ar gyfer anhwylder meddwl yn brif ddiben iddynt; a
- (b) y rhai lle y darperir triniaeth neu nyrsio (neu'r ddau) i bersonau sy'n agored i'w caethiwo o dan Ddeddf Iechyd Meddwl 1983.

#### Diogelwch cleifion ac eraill

47.—(1) Rhaid i'r datganiad o bolisiau a gweithdrefnau sydd i'w baratoi a'i weithredu gan y person cofrestredig yn unol â rheoliad 9(1)(d) gynnwys polisiau a gweithdrefnau mewn perthynas â'r canlynol—

- (a) asesu tueddiad claf tuag at drais a hunan-niwed;
- (b) darparu gwybodaeth i gyflogeion ynghylch canlyniad asesiad o'r fath;
- (c) asesu effaith cynllun safle mangre'r ysbyty, ei bolisiau a'i weithdrefnau, ar y risg y bydd claf yn niweidio ei hunan neu berson arall; ac
- (ch) darparu hyfforddiant i alluogi cyflogeion i leihau'r risg y bydd claf yn niweidio ei hun neu berson arall.

(2) Yn benodol, rhaid i'r person cofrestredig baratoi a gweithredu protocol ar hunanladdiad yn yr ysbyty sy'n ei gwneud yn ofynnol—

- (a) cynnal archwiliad cynhwysfawr o gyflwr meddwl pob claf;
- (b) gwerthuso hanes anhwylder meddwl y claf, gan gynnwys adnabod tueddiadau hunanladdol;
- (c) gwneud asesiad o dueddiad y claf i hunanladdiad; ac
- (ch) pan fo angen, cymryd camau priodol i leihau'r risg y gallai'r claf ladd ei hunan.

#### Ymwelwyr

48. Rhaid i'r person cofrestredig baratoi a gweithredu polisiau a gweithdrefnau ysgrifenedig yn yr ysbyty mewn perthynas â chleifion yn derbyn ymwelwyr.

- (d) precautions to be taken before and during use of a laser product or intense light source; and
- (e) action to be taken in the event of an accident, emergency, or other adverse incident.

### Chapter 3

#### Mental Health Hospitals

#### Application of regulations 47 to 50

46. Regulations 47 to 50 apply to independent hospitals of the following kinds—

- (a) those the main purpose of which is to provide medical or psychiatric treatment for mental disorder; and
- (b) those in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983.

#### Safety of patients and others

47.—(1) The statement of policies and procedures which is to be prepared and implemented by the registered person in accordance with regulation 9(1)(e) must include policies and procedures in relation to—

- (a) assessment of a patient's propensity to violence and self harm;
- (b) the provision of information to employees as to the outcome of such an assessment;
- (c) assessment of the effect of the layout of the hospital premises, and its policies and procedures, on the risk of a patient harming himself or another person; and
- (d) the provision of training to enable employees to minimise the risk of a patient harming himself or another person.

(2) The registered person must in particular prepare and implement a suicide protocol in the hospital which requires—

- (a) a comprehensive examination of the mental condition of each patient;
- (b) an evaluation of the patient's history of mental disorder, including identification of suicidal tendencies;
- (c) an assessment of the patient's propensity to suicide; and
- (d) if necessary, appropriate action to reduce the risk of the patient committing suicide.

#### Visitors

48. The registered person must prepare and implement written policies and procedures in the hospital in relation to patients receiving visitors.

## Cofnodion iechyd meddwl

49. Rhaid i'r person cofrestredig sicrhau y delir gafael ar unrhyw gofnodion y mae'n ofynnol eu gwneud o dan Reoliadau Iechyd Meddwl (Ysbyty, Gwarcheidiaeth, Triniaeth Gymunedol a Chydsynio i Driniaeth) (Cymru) 2008(1), ac sy'n ymwneud â chadw claf yn gaeth neu roi triniaeth i glaf mewn ysbyty annibynnol, am gyfnod o ddim llai na phum mlynedd sy'n dechrau ar y dyddiad pan fo'r person y mae'r cofnodion yn ymwneud ag ef yn peidio â bod yn glaf yn yr ysbyty.

## RHAN V

Gofynion Ychwanegol sy'n Gymwys i Glinigau Annibynnol

### Clinigau annibynnol

50. Pan fo clinig annibynnol yn darparu gofal cynenedigol i gleifion, rhaid i'r person cofrestredig sicrhau bod y proffesiynolyn gofal iechyd sy'n bennaf cyfrifol am ddarparu'r gofal hwnnw yn fydwraig, yn ymarferydd cyffredinol â chymwysterau priodol, neu'n ymarferydd meddygol â chymhwyster arbenigol mewn obstetreg.

## RHAN VI

Amrywiol

### Cydymffurfio â rheoliadau

51. Os oes rhagor nag un person cofrestredig mewn perthynas â sefydliad neu asiantaeth, ac os gwneir unrhyw beth y mae'n ofynnol i'r person cofrestredig ei wneud o dan y rheoliadau hyn gan un o'r personau cofrestredig, ni fydd yn ofynnol i'r peth hwnnw gael ei wneud gan unrhyw un o'r personau cofrestredig eraill.

### Tramgwyddau

52.–(1) Bydd torri, neu fethu â chydymffurfio ag unrhyw un o ddarpariaethau rheoliadau 6 i 17, 18(1), 19 i 35, 37 i 45 a 47 i 50 yn dramgwydd.

(2) Caiff yr awdurdod cofrestru ddwyn achos yn erbyn person a fu unwaith, ond nad yw bellach, yn berson cofrestredig, mewn perthynas â methiant i gydymffurfio â rheoliad 23 wedi i'r person hwnnw beidio â bod yn berson cofrestredig.

## Mental health records

49. The registered person must ensure that any records which are required to be made under the Mental Health (Hospital, Guardianship, Community Treatment and Consent to Treatment) (Wales) Regulations 2008(1), and which relate to the detention or treatment of a patient in an independent hospital, are kept for a period of not less than five years beginning on the date on which the person to whom they relate ceases to be a patient in the hospital.

## PART V

Additional Requirements Applying to Independent Clinics

### Independent clinics

50. Where an independent clinic provides antenatal care to patients, the registered person must ensure that the health care professional who is primarily responsible for providing that care is a midwife, an appropriately qualified general practitioner, or a medical practitioner with a specialist qualification in obstetrics.

## PART VI

Miscellaneous

### Compliance with regulations

51. Where there is more than one registered person in respect of an establishment or agency, anything which is required under these regulations to be done by the registered person will, if done by one of the registered persons, not be required to be done by any of the other registered persons.

### Offences

52.–(1) A contravention, or failure to comply with any of the provisions of regulation 6 to 17, 18(1), 19 to 35, 37 to 45 and 47 to 50 will be an offence.

(2) The registration authority may bring proceedings against a person who was once, but no longer is, a registered person, in respect of a failure to comply with regulation 23 after the person ceased to be a registered person.

(1) O.S. 2008/2439 (Cy.212).

(1) S.I. 2008/2439 (W.212).

## Darpariaethau trosiannol

53.–(1) Hyd nes bo digwyddiad cyfamserol yn digwydd, ni fydd rheoliad 27 yn gymwys i berson cofrestredig mewn cysylltiad ag ysbyty annibynnol nac i geisydd am gofrestrriad fel rheolwr, os caniatawyd cofrestriad y darparwr cofrestredig cyn 5 Ebrill 2011.

(2) At ddibenion y rheoliad hwn, ystyr "digwyddiad cyfamserol" ("*intervening event*") yw–

- (a) cais a ddaw i law'r awdurdod cofrestru o dan adran 12 o'r Ddeddf oddi wrth ddarparwr newydd yr ysbyty annibynnol; neu
- (b) cais a ddaw i law'r awdurdod cofrestru o dan adran 15(1)(a) o'r Ddeddf oddi wrth berson cofrestredig, pan fyddai effaith caniatáu'r cais fel a bennir ym mharagraff (3).

(3) Bydd cynnydd yn nifer y lleoedd cymeradwy y gall person cofrestredig eu darparu i gleifion sydd ag anabledd dysgu a ddiagnoswyd.

(4) Yn achos digwyddiad cyfamserol o dan baragraff (2)(b), ni fydd rheoliad 52 yn gymwys i reoliad 27 hyd nes mae'r cais yn cael ei benderfynu'n derfynol neu y'i tynnir yn ôl.

(5) At ddibenion paragraff (4) ystyr "cael ei benderfynu'n derfynol" ("*finally disposed of*") yw caniatáu'r cais o dan adran 15(4) neu, os gwrthodir y cais, y dyddiad ymhen 28 diwrnod ar ôl gwrthod y cais, ac os gwneir apêl, y dyddiad y penderfynir yr apêl yn derfynol neu y rhoddir y gorau iddi.

(6) Mae paragraff (7) yn gymwys i bersonau a gofrestrwyd mewn perthynas â sefydliad cyn 5 Ebrill 2011, pan fo–

- (a) rheoliad 3 yn gymwys mewn modd sy'n peri nad yw'r ysbyty annibynnol bellach yn ysbyty annibynnol; a
- (b) rheoliad 4 yn gymwys mewn perthynas â'r sefydliad hwnnw.

(7) Caiff personau y mae paragraff (6) yn gymwys iddynt–

- (a) parhau i redeg neu reoli'r sefydliad heb fod wedi eu cofrestru o dan y Ddeddf–
  - (i) yn ystod cyfnod o 3 mis sy'n dechrau ar 5 Ebrill 2011; a
  - (ii) os gwneir cais am gofrestrriad o fewn y cyfnod hwnnw, hyd nes mae'r cais yn cael ei benderfynu'n derfynol neu y'i tynnir yn ôl;

## Transitional provisions

53.–(1) Until such time as an intervening event takes place, regulation 27 does not apply to a person registered in respect of an independent hospital or to an applicant for registration as a manager where the registration of the registered provider was granted prior to 5 April 2011.

(2) For the purposes of this regulation, an "intervening event" ("*digwyddiad cyfamserol*") is–

- (a) an application received by the registration authority under section 12 of the Act from a new provider of the independent hospital; or
- (b) an application received by the registration authority under section 15(1)(a) of the Act from a registered person and the effect of the application being granted would be as specified in paragraph (3).

(3) There is an increase in the number of approved places that the registered person can provide to patients who have a diagnosed learning disability.

(4) In the case of an intervening event under paragraph (2)(b), regulation 52 will not apply to regulation 27 until such time as the application is finally disposed of or withdrawn.

(5) For the purpose of paragraph (4) "finally disposed of" ("*cael ei benderfynu'n derfynol*") means the grant of the application under section 15(4) or, in the case of a refusal of the application, the date 28 days following the refusal of the application and, if an appeal is made, the date when the appeal is finally determined or abandoned.

(6) Paragraph (7) applies to persons registered in respect of an establishment prior to 5 April 2011 where–

- (a) regulation 3 applies such that the independent hospital is no longer an independent hospital; and
- (b) regulation 4 applies in relation to that establishment.

(7) Persons to whom paragraph (6) applies–

- (a) may continue to carry on or manage the establishment without being registered under the Act–
  - (i) during a period of 3 months beginning the 5 April 2011; and
  - (ii) if within that period application is made for registration, until the application is finally disposed of or withdrawn;

(b) eu heithrio rhag talu ffi cofrestru o dan reoliad 3 o Reoliadau Gofal Iechyd Annibynnol (Ffioedd) (Cymru) 2011(1).

(8) At ddibenion paragraff (7)(a)(ii) ystyr "cael ei benderfynu'n derfynol" ("*finally disposed of*") yw'r dyddiad ymhen 28 diwrnod ar ôl caniatáu neu wrthod y cofrestrriad ac os gwneir apêl, y dyddiad y penderfynir yr apêl yn derfynol neu y rhoddir y gorau iddi.

### **Dirymu ac arbedion**

**54.**–(1) Yn ddarostyngedig i baragraff (2) dirymir drwy hyn Reoliadau Gofal Iechyd Preifat a Gwirfoddol (Cymru) 2002(2) ("Rheoliadau 2002").

(2) Mae rheoliad 3(4) o Reoliadau 2002 yn parhau i fod ag effaith.

(b) are excepted from payment of a registration fee under regulation 3 of the Independent Health Care (Fees) (Wales) Regulations 2011(1).

(8) For the purposes of paragraph (7)(a)(ii) "finally disposed of" ("cael ei benderfynu'n derfynol") means the date 28 days following the grant or refusal of registration and, if an appeal is made, the date when the appeal is finally determined or abandoned.

### **Revocation and savings**

**54.**–(1) Subject to paragraph (2) the Private and Voluntary Health Care (Wales) Regulations 2002(2) ("the 2002 Regulations") are hereby revoked.

(2) Regulation 3(4) of the 2002 Regulations continues to have effect.

*Edwina Hart*

Y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru

10 Mawrth 2011

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

10 March 2011

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(1) O.S. 2011/106 (Cy.25).

(2) O.S. 2002/325 (Cy.38).

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(1) S.I. 2011/106 (W.25).

(2) S.I. 2002/325 (W.38).

## ATODLEN 1

### Rheoliad 6

Gwybodaeth sydd i'w Chynnwys yn y Datganiad o Ddiben

1. Nodau ac amcanion y sefydliad neu'r asiantaeth.
2. Enw, cyfeiriad a manylion cyswllt teleffon, ffacs a phost electronig (os oes rai) y darparwr cofrestredig ac unrhyw reolwr cofrestredig.
3. Cymwysterau perthnasol a phrofiad perthnasol y darparwr cofrestredig ac unrhyw reolwr cofrestredig.
4. Yn achos corff, manylion swyddogaethau a chyfrifoldebau'r unigolyn cyfrifol o fewn y corff.
5. Nifer, cymwysterau perthnasol a phrofiad y staff sy'n gweithio yn y sefydliad neu at ddibenion yr asiantaeth.
6. Strwythur trefniadol y darparwr cofrestredig.
7. Y mathau o driniaeth, cyfleusterau a'r holl wasanaethau eraill y darperir ar eu cyfer yn, neu at ddibenion y sefydliad neu'r asiantaeth, gan gynnwys manylion yr ystod o anghenion y bwriadwyd i'r gwasanaethau hynny eu bodloni ac sydd ar gael er budd y cleifion.
8. The trefniadau a wnaed ar gyfer ceisio safbwyntiau'r cleifion ynglŷn ag ansawdd y gwasanaethau a ddarperir gan y sefydliad neu'r asiantaeth.
9. Y trefniadau a wnaed ar gyfer cyswllt rhwng unrhyw gleifion mewnol a'u perthnasau, cyfeillion a chynrychiolwyr, gan gynnwys unrhyw gyfyngiadau ar oriau ymweld.
10. Y trefniadau ar gyfer delio â chwynion, fel a bennir yn rheoliad 24.
11. Y trefniadau ar gyfer parchu preifatrwydd ac urddas cleifion.
12. Y dyddiad yr ysgrifennwyd y datganiad o ddiben, ac os diwygir ef yn unol â rheoliad 8(a), dyddiad y cyfryw ddiwygio.

## SCHEDULE 1

### Regulation 6

Information to be included in the Statement of Purpose

1. The aims and objectives of the establishment or agency.
2. The name, address, telephone, fax and electronic mail contact details (if any) of the registered provider and of any registered manager.
3. The relevant qualifications and relevant experience of the registered provider and any registered manager.
4. In the case of an organisation, details of the responsible individual's roles and responsibilities within the organisation.
5. The number, relevant qualifications and experience of the staff working in the establishment or for the purposes of the agency.
6. The registered provider's organisational structure.
7. The kinds of treatment, facilities and all other services provided for in or for the purposes of the establishment or agency, including details of the range of needs which those services are intended to meet and which are available for the benefit of patients.
8. The arrangements made for seeking patients' views about the quality of services provided by the establishment or agency.
9. The arrangements made for contact between any in-patients and their relatives, friends and representatives including any limitations on visiting hours.
10. The arrangements for dealing with complaints as set out in regulation 24.
11. The arrangements for respecting the privacy and dignity of patients.
12. The date the statement of purpose was written and, where revised in accordance with regulation 8(a), the date of such revision.

## ATODLEN 2

Rheoliadau 10(3), 12(2) a 21(2)

Yr wybodaeth sy'n ofynnol ynglŷn â phersonau sy'n bwriadu rhedeg, rheoli neu weithio mewn sefydliad neu asiantaeth

1. Prawf pendant o bwy yw'r person, gan gynnwys ffotograff diweddar.

2. Naill ai—

- (a) pan fo angen y dystysgrif at ddiben sy'n ymwneud â chofrestru o dan Ran 2 o'r Ddeddf neu pan fo'r swydd yn dod o fewn rheoliad 5A o Reoliadau Deddf yr Heddlu 1997 (Cofnodion Troseddol) 2002, tystysgrif cofnod troseddol fanylach a ddyroddwyd o dan adran 113B o Ddeddf yr Heddlu 1997(1), sy'n cynnwys, fel y bo'n gymwys, gwybodaeth addasrwydd mewn perthynas ag oedolion hygwlwyf (o fewn ystyr "*suitability information relating to vulnerable adults*" yn adran 113BB(2) o'r Ddeddf honno) neu wybodaeth addasrwydd mewn perthynas â phlant (o fewn ystyr "*suitability information relating to children*" yn adran 113BA(2) o'r Ddeddf honno) neu'r ddwy, a rhaid bod llai na thair blynedd wedi mynd heibio er pan ddyroddwyd y dystysgrif; neu
- (b) mewn unrhyw achos arall, tystysgrif cofnod troseddol a ddyroddwyd o dan adran 113A o Ddeddf yr Heddlu 1997, a rhaid bod llai na thair blynedd wedi mynd heibio er pan ddyroddwyd y dystysgrif,

ac mae cyfeiriadau at Ddeddf yr Heddlu 1997 yn cynnwys cyfeiriadau at y Ddeddf honno fel y'i diwygiwyd o bryd i'w gilydd.

3. Naill ai—

- (a) pan fo angen y dystysgrif at ddiben sy'n ymwneud â chofrestru o dan Ran 2 o'r Ddeddf neu pan fo'r swydd yn dod o fewn rheoliad 5A o Reoliadau Deddf yr Heddlu 1997 (Cofnodion Troseddol) 2002, tystysgrif cofnod troseddol fanylach a ddyroddwyd o dan adran 113B o Ddeddf yr Heddlu 1997 sy'n cynnwys, fel y bo'n gymwys, gwybodaeth addasrwydd mewn perthynas ag oedolion hygwlwyf (o fewn ystyr "*suitability information relating to vulnerable adults*" yn adran 113BB(2) o'r Ddeddf honno) neu wybodaeth addasrwydd mewn perthynas â phlant (o fewn ystyr "*suitability information relating to children*" yn adran 113BA(2) o'r Ddeddf honno); neu
- (b) mewn unrhyw achos arall, tystysgrif cofnod troseddol a ddyroddwyd o dan adran 113A o Ddeddf yr Heddlu 1997,

## SCHEDULE 2

Regulations 10(3), 12(2) and 21(2)

Information required in respect of persons seeking to carry on, manage or work at an establishment or agency

1. Positive proof of identity including a recent photograph.

2. Either—

- (a) where the certificate is required for a purpose related to registration under Part 2 of the Act or the position falls within regulation 5A of the Police Act 1997 (Criminal Records) Regulations 2002, an enhanced criminal record certificate issued under section 113B of the Police Act 1997(1) which includes, as applicable, suitability information relating to vulnerable adults (within the meaning of section 113BB(2) of that Act) or suitability information relating to children (within the meaning of section 113BA(2) of that Act) or both, in respect of which less than three years have elapsed since it was issued; or
- (b) in any other case, a criminal record certificate issued under section 113A of the Police Act 1997 in respect of which less than three years have elapsed since it was issued,

and references to the Police Act 1997 include references to that Act as amended from time to time.

3. Either—

- (a) where the certificate is required for a purpose related to registration under Part 2 of the Act or the position falls within regulation 5A of the Police Act 1997 (Criminal Records) Regulations 2002, an enhanced criminal record certificate issued under section 113B of the Police Act 1997 which includes, as applicable, suitability information relating to vulnerable adults (within the meaning of section 113BB(2) of that Act) or suitability information relating to children (within the meaning of section 113BA(2) of that Act); or
- (b) in any other case, a criminal record certificate issued under section 113A of the Police Act 1997,



ac mae cyfeiriadau at Ddeddf yr Heddlu 1997 yn cynnwys cyfeiriadau at y Ddeddf honno fel y'i diwygiwyd o bryd i'w gilydd.

4. Geirdaon ysgrifenedig oddi wrth y naill a'r llall o ddau gyflogwr diweddaraf y person.

5. Os bu'r person yn gweithio'n flaenorol mewn swydd a oedd yn cynnwys gweithio gyda phlant neu oedolion hygwlwyf, cadarnhad, i'r graddau y bo'n rhesymol ymarferol, o'r rhesymau pam y daeth y gyflogaeth neu'r swydd honno i ben.

6. Tystiolaeth ddogfennol o unrhyw gymhwyster perthnasol.

7. Hanes cyflogaeth llawn, ynghyd ag esboniad ysgrifenedig boddhaol o unrhyw fylchau mewn cyflogaeth.

8. Os yw'r person yn broffesiynolyn gofal iechyd, manylion cofrestrriad y person gyda'r corff (os oes un) sy'n gyfrifol am reoleiddio aelodau o'r proffesiwn gofal iechyd hwnnw.

and references to the Police Act 1997 include references to that Act as amended from time to time.

4. Written references from each of the person's two most recent employers.

5. Where a person has previously worked in a position which involved work with children or vulnerable adults, verification, so far as reasonably practicable, of the reason why the employment or position ended.

6. Documentary evidence of any relevant qualification.

7. A full employment history, together with a satisfactory written explanation of any gaps in employment.

8. Where the person is a health care professional, details of the person's registration with the body (if any) responsible for regulation of members of the health care profession in question.

## RHAN 1

## PART 1

Y cyfnod y mae'n rhaid dal gafael ar Gofnodion Meddygol

Period for which Medical Records must be Retained

<b>Math o glaf</b>	<b>Cyfnod dal gafael lleiaf</b>	<b>Type of patient</b>	<b>Minimum period of retention</b>
(a) Claf a oedd o dan 17 oed ar y dyddiad pan ddaeth y driniaeth y mae'r cofnodion yn cyfeirio ati i ben.	Hyd at ben-blwydd y claf yn 25	(a) Patient who was under the age of 17 at the date on which the treatment to which the records refer was concluded	Until the patient's 25th birthday
(b) Claf a oedd yn 17 oed ar y dyddiad pan ddaeth y driniaeth y mae'r cofnodion yn cyfeirio ati i ben.	Hyd at ben-blwydd y claf yn 26	(b) Patient who was aged 17 at the date on which the treatment to which the records refers was concluded	Until the patient's 26th birthday
(c) Claf a fu farw cyn cyrraedd 18 oed	Cyfnod o 8 mlynedd sy'n dechrau ar ddyddiad marwolaeth y claf	(c) Patient who died before attaining the age of 18	A period of 8 years beginning on the date of patient's death
(ch) Claf a dderbyniodd driniaeth am anhwylder meddwl yn ystod y cyfnod y cyfeirir ato yn y cofnodion	Cyfnod o 20 mlynedd sy'n dechrau ar ddyddiad yr eitem olaf yn y cofnod	(d) Patient who was treated for mental disorder during the period to which the records refer	A period of 20 years beginning on the date of the last entry in the record
(d) Claf a dderbyniodd driniaeth ar gyfer anhwylder meddwl yn ystod y cyfnod y cyfeirir ato yn y cofnodion ac a fu farw tra'n derbyn y driniaeth honno	Cyfnod o 8 mlynedd sy'n dechrau ar ddyddiad marwolaeth y claf	(e) Patient who was treated for mental disorder during the period to which the records refer and who died whilst receiving that treatment	A period of 8 years beginning on the date of the patient's death
(dd) Claf y mae ei gofnodion yn ymwneud â thriniaeth gan ymarferydd cyffredinol	Cyfnod o 10 mlynedd sy'n dechrau ar ddyddiad yr eitem olaf yn y cofnod	(f) Patient whose records relate to treatment by a general practitioner	A period of 10 years beginning on the date of the last entry in the record
(e) Claf a gafodd drawsblaniad organ	Cyfnod o 11 mlynedd sy'n dechrau ar ddyddiad marwolaeth y claf neu ei ryddhau, pa un bynnag yw'r cynharaf	(g) Patient who has received an organ transplant	A period of 11 years beginning on the date of the patient's death or discharge whichever is the earlier

(f) Cleifion sy'n cymryd rhan mewn treialon clinigol	Cyfnod o 15 mlynedd sy'n dechrau ar ddyddiad cwblhau'r driniaeth
(ff) Pob achos arall	Cyfnod o 8 mlynedd sy'n dechrau ar ddyddiad yr eitem olaf yn y cofnod

(h) Patients involved in clinical trials	A period of 15 years beginning with the date of conclusion of treatment
(i) All other cases	A period of 8 years beginning on the date of the last entry in the record

## RHAN 11

Cofnodion sydd i'w cynnal ar gyfer Arolygu

### 1. Cofrestr o'r cleifion, sy'n cynnwys—

- (a) enw, cyfeiriad, rhif teleffon, dyddiad geni a statws priodasol neu bartneriaeth sifil pob claf;
- (b) enw, cyfeiriad a rhif teleffon perthynas agosaf y claf neu unrhyw berson a awdurdodir gan y claf i weithredu ar ran y claf;
- (c) enw, cyfeiriad a rhif teleffon ymarferydd cyffredinol y claf;
- (ch) pan fo'r claf yn blentyn, enw a chyfeiriad yr ysgol lle mae'r plentyn yn ddisgybl, neu lle bu'n ddisgybl cyn ei dderbyn i sefydliad;
- (d) pan fo claf wedi ei dderbyn i warcheidiaeth o dan Ddeddf Iechyd Meddwl 1983, enw, cyfeiriad a rhif teleffon y gwarcheidwad;
- (dd) enw a chyfeiriad unrhyw gorff a drefnodd bod y claf yn cael ei dderbyn neu a drefnodd ei driniaeth;
- (e) y dyddiad y derbyniwyd y claf i sefydliad, neu y cafodd y driniaeth a ddarparwyd at ddibenion sefydliad neu at ddibenion asiantaeth am y tro cyntaf;
- (f) natur y driniaeth a gafodd y claf, neu y'i derbyniwyd ar ei chyfer;
- (ff) os bu'r claf yn glaf mewnlol mewn ysbyty annibynnol, y dyddiad y'i rhyddhawyd;
- (g) os trosglwyddwyd y claf i ysbyty (gan gynnwys ysbyty gwasanaeth iechyd), dyddiad y trosglwyddiad, y rhesymau dros y trosglwyddiad ac enw'r ysbyty y trosglwyddwyd y claf iddo;
- (h) os bydd farw'r claf tra mewn sefydliad neu yn ystod triniaeth a ddarperir at ddibenion sefydliad neu asiantaeth, dyddiad, amser ac achos ei farwolaeth.

### 2. Cofrestr o'r holl driniaethau llawfeddygol a gyflawnir mewn sefydliad, sy'n cynnwys—

- (a) enw'r claf y cyflawnwyd y llawdriniaeth arno;
- (b) natur y weithdrefn lawdriniaethol a'r dyddiad y digwyddodd;

## PART 11

Records to be Maintained for Inspection

### 1. A register of patients, including—

- (a) the name, address, telephone number, date of birth and marital status or civil partnership status of each patient;
- (b) the name, address and telephone number of the patient's next of kin or any person authorised by the patient to act on the patient's behalf;
- (c) the name, address and telephone number of the patient's general practitioner;
- (d) where the patient is a child, the name and address of the school which the child attends or attended before admission to an establishment;
- (e) where a patient has been received into guardianship under the Mental Health Act 1983, the name, address and telephone number of the guardian;
- (f) the name and address of any body which arranged the patient's admission or treatment;
- (g) the date on which the patient was admitted to an establishment or first received treatment provided for the purposes of an establishment or for the purposes of an agency;
- (h) the nature of the treatment received by the patient or for which the patient was admitted;
- (i) where the patient has been an in-patient in an independent hospital, the date of the patient's discharge;
- (j) if the patient has been transferred to a hospital (including a health service hospital), the date of the transfer, the reasons for it and the name of the hospital to which the patient was transferred;
- (k) if the patient dies whilst in an establishment or during treatment provided for the purposes of an establishment or agency, the date, time and cause of death.

### 2. A register of all surgical operations performed in an establishment, including—

- (a) the name of the patient on whom the operation was performed;
- (b) the nature of the surgical procedure and the date on which it took place;

- (c) enw'r ymarferydd meddygol neu'r deintydd a gyflawnodd y llawdriniaeth;
- (ch) enw'r anesthetydd a oedd yn bresennol;
- (d) enw a llofnod y person a oedd yn gyfrifol am wirio bod pob nodwydd, swab a chyfarpar a ddefnyddiwyd yn y llawdriniaeth wedi'u cymryd yn ôl o'r claf;
- (dd) manylion pob dyfais feddygol a fewnblannwyd yn y claf, ac eithrio pan olygai hynny ddatgelu gwybodaeth yn groes i ddarpariaethau adran 33A(1)(e), (f) ac (g) o Ddeddf Ffrwythloni Dynol ac Embryoleg 1990(1) (datgelu gwybodaeth).

3. Cofrestr o bob cyfarpar mecanyddol a thechnegol a ddefnyddir at ddibenion triniaethau a ddarperir gan y sefydliad, sy'n cynnwys—

- (a) dyddiad prynu'r cyfarpar;
- (b) dyddiad gosod y cyfarpar;
- (c) manylion cynnal a chadw'r cyfarpar a'r dyddiadau pan wnaed gwaith cynnal a chadw.

4. Cofrestr o bob digwyddiad y mae'n rhaid hysbysu'r awdurdod cofrestru ohonynt yn unol â rheoliadau 29 a 30.

5. Cofnod o'r shifftiau rota a drefnwyd ar gyfer pob cyflogai a chofnod o'r oriau a weithiodd bob person mewn gwirionedd.

6. Cofnod o bob person a gyflogir yn y sefydliad neu at ddibenion y sefydliad neu at ddiben yr asiantaeth, a rhaid i'r cofnod hwnnw gynnwys y materion canlynol mewn perthynas ag unigolyn a ddisgrifir yn rheoliad 21(1)—

- (a) enw a dyddiad geni y person;
- (b) manylion swydd y person yn y sefydliad;
- (c) dyddiadau ei gyflogaeth; ac
- (ch) yn achos proffesiynolyn gofal iechyd, manylion ei gymwysterau proffesiynol perthnasol a chofrestriad y person gyda'r corff rheoleiddiol proffesiynol perthnasol.

- (c) the name of the medical practitioner or dentist by whom the operation was performed;
- (d) the name of the anaesthetist in attendance;
- (e) the name and signature of the person responsible for checking that all needles, swabs and equipment used during the operation have been recovered from the patient;
- (f) details of all implanted medical devices, except where this would entail the disclosure of information contrary to the provisions of section 33A(1)(e), (f) and (g) of the Human Fertilisation and Embryology Act 1990(1) (disclosure of information).

3. A register of all mechanical and technical equipment used for the purposes of treatment provided by the establishment or agency, including—

- (a) the date of purchase of the equipment;
- (b) the date of installation of the equipment;
- (c) details of maintenance of the equipment and the dates on which maintenance work was carried out.

4. A register of all events which must be notified to the registration authority in accordance with regulations 29 and 30.

5. A record of the rostered shifts for each employee and a record of the hours actually worked by each person.

6. A record of each person employed in or for the purposes of the establishment or purpose of the agency, which must include in respect of an individual described in regulation 21(1) the following matters—

- (a) the person's name and date of birth;
- (b) details of the person's position in the establishment;
- (c) dates of employment; and
- (d) in respect of a health care professional, details of relevant professional qualifications and registration with the relevant professional regulatory body.

**RHAN 1**

Y manylion sydd i'w cofnodi mewn perthynas â chleifion sy'n cael gwasanaethau obstetrig

1. Dyddiad ac amser geni plentyn pob claf, nifer y plant a anwyd i'r claf, rhyw pob plentyn, a pha un a oedd yr enedigaeth yn enedigaeth fyw neu'n farw-enedigaeth.
2. Enw a chymwysterau'r person a fu'n colwyno'r claf.
3. Dyddiad ac amser unrhyw gamesgor a ddigwyddodd yn yr ysbyty.
4. Y dyddiad y mae unrhyw blentyn a enir i glaf yn gadael yr ysbyty.
5. Os bu farw yn yr ysbyty unrhyw blentyn a aned i glaf, dyddiad ac amser ei farwolaeth.

**RHAN II**

Y manylion sydd i'w cofnodi mewn perthynas â phlentyn a enir mewn ysbyty annibynnol

6. Manylion pwysau a chyflwr y plentyn adeg yr enedigaeth.
7. Datganiad dyddiol o iechyd y plentyn.
8. Os cyflawnir unrhyw archwiliad pediatrig sy'n cynnwys unrhyw un o'r gweithdrefnau canlynol—
  - (a) archwilio am annormaledd cynhwynol gan gynnwys datgymaliad cynhwynol o'r glun;
  - (b) mesur cylchedd pen y plentyn;
  - (c) mesur hyd y plentyn;
  - (ch) sgrinio am ffenylcetonwria;
  - (d) sgrinio am hypothyroidedd cynhwynol;
  - (dd) sgrinio am ffibrosis systig;
  - (e) sgrinio am glefyd cryman-gell;
  - (f) sgrinio am y diffyg dehydrogenas acyl-CoA cadwyn-ganolig;

manylyon y cyfryw archwiliad a'r canlyniad.

**PART 1**

Details to be Recorded in Respect of Patients Receiving Obstetric Services

1. The date and time of delivery of each patient, the number of children born to the patient, the sex of each child and whether the birth was a live birth or a stillbirth.
2. The name and qualifications of the person who delivered the patient.
3. The date and time of any miscarriage occurring in the hospital.
4. The date on which any child born to a patient left the hospital.
5. If any child born to a patient died in the hospital, the date and time of death.

**PART II**

Details to be Recorded in Respect of a Child Born in an Independent Hospital

6. Details of the weight and condition of the child at birth.
7. A daily statement of the child's health.
8. If any paediatric examination is carried out involving any of the following procedures—
  - (a) examination for congenital abnormalities including congenital dislocation of the hip;
  - (b) measurement of the circumference of the head of the child;
  - (c) measurement of the length of the child;
  - (d) screening for phenylketonuria;
  - (e) screening for congenital hypothyroidism;
  - (f) screening for cystic fibrosis;
  - (g) screening for sickle cell disease;
  - (h) screening for medium-chain acyl-CoA dehydrogenase deficiency;

details of such examination and the result.

