OFFERYNNAU STATUDOL CYMRU

2010 Rhif 868 (Cy.90)

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2010

Gwnaed - - - - *18 Mawrth 2010*
Gosodwyd gerbron Cynulliad Cenedlaethol Cymru - - *19 Mawrth 2010*
Yn dod i rym - - *1 Ebrill 2010*

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddwyd iddynt gan adrannau 80, 83, 86, 121 a 203(9) a (10) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006(**1**), drwy hyn yn gwneud y Rheoliadau canlynol:

Enwi, cychwyn, cymhwyso a dehongli

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2010 a deuant i rym ar 1 Ebrill 2010.

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

(3) Yn y Rheoliadau hyn, ystyr "y prif Reoliadau" ("*the principal Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(**2**).

Diwygio'r prif Reoliadau

2.—(1) Diwygir y prif Reoliadau yn unol â darpariaethau canlynol y rheoliad hwn.

(2) Yn rheoliad 2(1) (dehongli) o'r prif Reoliadau, yn y man priodol yn nhrefn yr wyddor, mewnosoder—

""advanced electronic signature" means an electronic signature which is—

(a) uniquely linked to the signatory;

(b) capable of identifying the signatory;

(c) created using means that the signatory can maintain under his sole control; and

(d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;";

(**1**) 2006 p.42.
(**2**) O.S.1992/662 Yr offerynnau perthnasol sy'n ei ddiwygio yw O.S. 2007/205 (Cy.19) ac O.S. 2009/1491 (Cy.144).

““appliance” means an appliance which is included in a list for the time being approved by the Welsh Ministers for the purposes of section 80 (arrangements for pharmaceutical services) of the 2006 Act;”;

““appliance use review service” means arrangements made in accordance with section 81 of the 2006 Act (arrangements for additional Pharmaceutical Services) for a pharmacist or specialist nurse to review a person’s use of any specified appliance;”;

““associated batch issue” means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;”;

““batch issue” means a form provided by a Local Health Board and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services which is in the required format, and which—

(a) is generated by a computer and not signed by a repeatable prescriber;

(b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;

(c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and

(d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);”;

““contingent removal” means removal from a pharmaceutical list contingently, within the meaning of section 108 (contingent removal) of the 2006 Act, and “contingently remove” shall be construed accordingly;”;

““electronic prescription” means an electronic prescription form or an electronic repeatable prescription;”;

““electronic prescription form” means a prescription which falls within paragraph (b) of the definition of “prescription form;”;

““electronic repeatable prescription” means a prescription which falls within paragraph (a)(ii) of the definition of “repeatable prescription;”;

““employment” means any employment whether paid or unpaid and whether under a contract for services or a contract of service, and “employed” and “employer” shall be construed accordingly;”;

““equivalent body” means a Primary Care Trust in England, a Health Board or an NHS trust in Scotland, a Health and Social Services Board in Northern Ireland, (in relation to any time prior to 1 October 2002) a Strategic Health Authority in England or (in relation to any time prior to 1st April 2003) a Health Authority in Wales or an NHS trust in England or in Wales;”;

““equivalent lists” means lists kept by an equivalent body;”;

““ESP scheme” means an Essential Small Pharmacies Local Pharmaceutical Services scheme;”;

““ETP service” means the 2-dimensional barcoded prescription service which forms part of the information technology systems in prescribing and dispensing systems in Wales and used by the health service in Wales to transfer and hold prescription information relating to patients;”.

““fraud case” means a case where a person meets the second condition for removal from the pharmaceutical list, set out in section 107(3) (disqualification of practitioners) of the 2006 Act, or by virtue of section 109 (fraud and unsuitability cases: supplementary) of the 2006 Act is treated as doing so;”;

““health care professional” means a person who is a member of a profession regulated by a body mentioned in section 25 of the National Health Service Reform and Healthcare Professions Act 2002(**3**);”;

““licensing or regulatory body” means a body that licenses or regulates any profession of which the person is or has been a member, and includes any body which licenses or regulates any such profession in a country other than the United Kingdom;”;

““list”, unless the context otherwise requires, means —

(a) a list referred to in section 115(1) (national disqualification) of the 2006 Act;

(b) a list of persons undertaking to provide general medical services prepared in accordance with regulations made under section 29 (arrangements and regulations for general medical services) of the Act, as the list existed on or before 31 March 2004;

(c) a list of persons approved by a Local Health Board for the purpose of assisting in the provision of general medical services prepared in accordance with regulations made under section 43D(1) (supplementary lists) of the Act as the list existed on or before 31 March 2004; or

(d) a services list referred to in section 8ZA(1)(a) (lists of persons who may perform personal medical services or personal dental services) of the 1997 Act as the list existed on or before 31 March 2004;”;

““LPS chemist” means—

(a) a registered pharmacist,

(b) a person lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(**4**), or

(c) a supplier of appliances,

who provides local pharmaceutical services under a pharmacy scheme or an LPS scheme;”;

““LPS scheme” has the same meaning as in paragraph 1(2) of Schedule 7 to the 2006 Act;”;

““NHS Business Services Authority” means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**5**);”;

““NHS Individual Health Record” means the records relating to an individual patient held by the NHS individual Health Record Service;”;

““NHS Individual Health Record Service” means the information technology systems which hold medical records relating to patients in Wales;”;

““NHS services” means services provided as part of the health service in Wales;”;

““National Health Service Counter Fraud and Security Management Service” means the NHS Business Services Authority;”;

““non-electronic prescription form” means a prescription form which falls within paragraph (a) of the definition of “prescription form;”;

““non-electronic repeatable prescription” means a prescription which falls within paragraph (a)(i) of the definition of repeatable prescription;”;

““originating events” means the events that gave rise to the conviction, investigation, proceedings, suspension, refusal to admit, conditional inclusion, removal or contingent removal that took place;”;

(**3**) 2002 p.17.
(**4**) 1968 p.67.
(**5**) O.S. 2005/2414.

""professional conduct" includes matters relating both to professional conduct and professional performance;";

""specified appliance" means —

(a) any of the following appliances listed in Part IXA of the Drug Tariff —

(i) a catheter appliance (including a catheter accessory and maintenance solution),

(ii) a laryngectomy or tracheostomy appliance,

(iii) an anal irrigation system,

(iv) a vacuum pump or constrictor ring for erectile dysfunction, or

(v) a wound drainage pouch;

(b) an incontinence appliance listed in Part IXB of the Drug Tariff; or

(c) a stoma appliance listed in Part IXC of the Drug Tariff;".

""stoma appliance customisation" means the customisation of a quantity of more than one stoma appliance, where —

(a) the stoma appliances to be customised are listed in Part IXC of the Drug Tariff;

(b) the customisation involves modification to the same specification of multiple identical parts for use with each appliance; and

(c) that modification is based on the patient's measurements or a record of those measurements and, if applicable, a template;"; and

""supplier of appliances" means a person with whom a Local Health Board has entered into arrangements for the provision of pharmaceutical services, being terms of service under regulation 3;".

(3) Yn rheoliad 2(1) o'r prif Reoliadau yn lle'r diffiniad o "local pharmaceutical services" rhodder —

""local pharmaceutical services" means local pharmaceutical services under —

(a) an LPS scheme established under paragraph 1(1) of Schedule 7 to the 2006 Act; or

(b) an ESP scheme;";

(4) Yn rheoliad 2(1) o'r prif Reoliadau, yn lle'r diffiniad o "prescription form" rhodder—

""prescription form" means—

(a) a form provided by a Health Board, a Health and Social Services Board, a Local Health Board, a Primary Care Trust, an NHS Trust or NHS Foundation Trust, and issued by a prescriber; or

(b) a form containing data that are created in an electronic format, uniquely identified using a prescriber's code and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service,

to enable a person to obtain pharmaceutical services or local pharmaceutical services, and does not include a repeatable prescription".

(5) Yn rheoliad 2(1) o'r prif Reoliadau, yn lle'r diffiniad o "repeatable prescriber" rhodder—

""repeatable prescriber" means a person who is—

(a) a pharmacist independent prescriber who—

(i) is included in a pharmaceutical list, and —

(aa) with whom a Local Health Board has made an arrangement for the provision of a directed service which is an independent prescribing service; and

(bb) who is issuing or creating a repeatable prescription as part of that arrangement;

(ii) is employed or engaged by a person who is included in a pharmaceutical list, and —

(aa) a Local Health Board has made an arrangement with that person for the provision of a directed service which is an independent prescribing service; and

(bb) the pharmacist independent prescriber is issuing or creating a repeatable prescription as part of that arrangement;

(iii) is a party to an LPS scheme or LPS arrangements, and —

(aa) with whom a Local Health Board has made an arrangement for the provision of an Independent Prescribing Service; and

(bb) who is issuing or creating a repeatable prescription as part of that arrangement; or

(iv) is employed or engaged by a party to an LPS scheme or LPS arrangements (other than a Local Health Board), and —

(aa) a Local Health Board has made an arrangement with that party for the provision of an independent prescribing service; and

(bb) the pharmacist independent prescriber is issuing or creating a repeatable prescription as part of that arrangement;".

(6) Yn rheoliad 2(1) o'r prif Reoliadau, yn lle'r diffiniad o "repeatable prescription" rhodder—

""repeatable prescription" means a prescription contained in a form provided by a Local Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services which is in the format specified in Part I of Schedule 1 to the NHS (General Medical Services Contracts) (Wales) Regulations 2004(**6**) and which is either —

(a) (i) generated by a computer but signed by a prescriber; or

(ii) a form containing data that are created in an electronic format, identified using a repeatable prescriber's code and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service;

(b) is issued or created to enable a person to obtain pharmaceutical services or local pharmaceutical services; and

(c) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;".

(7) Yn rheoliad 2(1)(c) o'r prif Reoliadau, ar ôl y geiriau "where these words occur", ychwaneger —

"except in the definition of "equivalent body"".

Diwygio Atodlen 2 i'r prif Reoliadau

3. Diwygir Atodlen 2 i'r prif Reoliadau yn unol â rheoiadau 4 i 13.

Diwygio paragraff 1

4. Dileer is-baragraff 1(2) o Atodlen 2 i'r prif Reoliadau ac ailrifer is-baragraff 1(3) fel 1(2).

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