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WELSH STATUTORY INSTRUMENTS

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**2008 No. 3239**

**The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008**

**PART 1**

Preliminary

**Title, commencement and application**

1.—(1) The title of these Regulations is the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008.

(2) These Regulations come into force on 9 January 2009.

(3) These Regulations apply in relation to Wales.

**Commencement Information**

**II** Reg. 1 in force at 9.1.2009, see [reg. 1\(2\)](#)

**Interpretation**

2.—(1) In these Regulations—

“the 2000 Act” (“*Deddf 2000*”) means the Care Standards Act 2000(1);

“the 2003 Act” (“*Deddf 2003*”) means the Health and Social Care (Community Health and Standards) Act 2003(2);

“the 2006 Act” (“*Deddf 2006.*”) means the Health Act 2006(3);

“accountable officer” (“*swyddog atebol*”) means a person nominated or appointed under regulation 4;

“CSSIW” (“*AGGCC*”) means the Care and Social Services Inspectorate for Wales(4);

“designated body” (“*corff dynodedig*”) is to be construed in accordance with regulation 3;

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“Health Solutions Wales” (“*Atebion Iechyd Cymru*”) is a division of the Velindre National Health Service Trust whose prescribing services branch provides data entry and pricing services relating to prescriptions dispensed in Wales;

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(1) 2000 c. 14.

(2) 2003 c. 43.

(3) 2006 c. 28.

(4) The Care and Social Services Inspectorate Wales (“CSSIW”) is an operationally distinct division of the Department of Public Services and Performance within the Welsh Assembly Government.

- “HIW” (“*AGIC*”) means the Healthcare Inspectorate for Wales<sup>(5)</sup>;
- “the health service” (“*y gwasanaeth iechyd*”) means the health service established in pursuance of the National Health Service Act 1946<sup>(6)</sup>;
- [<sup>F2</sup>“local authority” (“*awdurdod lleol*”) has the same meaning as in section 197 of the Social Services and Well-being (Wales) Act 2014;]
- “local intelligence network” (“*rhwydwaith gwybodaeth leol*”) is to be construed in accordance with regulation 18(2);
- “Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a Local Health Board established by an Order under section 11(1) of the National Health Service (Wales) Act 2006<sup>(7)</sup>;
- “misuse of drugs legislation” (“*deddfwriaeth am gamddefnyddio cyffuriau*”) means the Misuse of Drugs Act 1971<sup>(8)</sup> and any subordinate legislation made under that Act;
- “NHS Business Services Authority” (“*Awdurdod Gwasanaethau Busnes y GIG*”) means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005<sup>(9)</sup>;
- “NHS Trust” (“*Ymddiriedolaeth GIG*”) means a National Health Service Trust established by an Order under section 18(1) of the NHS (Wales) Act 2006;
- “NHS (Wales) Act 2006” (“*Deddf GIG (Cymru) 2006*”) means the National Health Service (Wales) Act 2006;
- “registered dentist” (“*deintydd cofrestredig*”) means a person who is registered in the dentists register kept under section 14 of the Dentists Act 1984<sup>(10)</sup> (the dentists register and registrar);
- [<sup>F3</sup>“registered pharmacist” (“*fferyllydd cofrestredig*”) means a person registered as a pharmacist in Part 1 or 4 of the register maintained by the General Pharmaceutical Council under article 19 of the Pharmacy Order 2010;]
- “retail pharmacy business” (“*busnes manwerthu fferyllol*”) has the meaning given in section 132 of the Medicines Act 1968<sup>(11)</sup> (registration of premises);
- [<sup>F4</sup>“registered pharmacy” (“*fferyllfa gofrestrdig*”) means a retail pharmacy business in Wales that is for the time being entered in Part 3 of the register maintained by the General Pharmaceutical Council under article 19 of the Pharmacy Order 2010 (registration of premises);]
- “regulatory body” (“*corff rheoleiddiol*”) means a body referred to in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 (the Council for the Regulation of Health Care Professionals)<sup>(12)</sup>;
- “relevant premises” (“*mangre berthnasol*”) is to be construed in accordance with regulation 20;
- “responsible body” (“*corff cyfrifol*”), unless the context otherwise requires, is to be construed in accordance with regulation 22;
- [<sup>F5</sup>“the UK GDPR” (“*GDPR y DU*”) has the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(10) and (14) of that Act);]

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(5) The Healthcare Inspectorate Wales (“HIW”) is an operationally distinct division of the Department of Public Services and Performance within the Welsh Assembly Government.

(6) 1946 c. 81. This Act was repealed by the National Health Service Act 1977, which was in turn repealed in relation to Wales by the National Health Service (Wales) Act 2006 (c. 42) (“the NHS (Wales) Act 2006”).

(7) 2006 c. 42.

(8) 1971 c. 38.

(9) S.I.2005/3361

(10) 1984 c. 24.

(11) 1968 c. 67. There are amendments to section 132 which are not relevant to the definition of “retail pharmacy business”.

(12) 2002 c. 17.

“Welsh Ambulance Services NHS Trust (“*Ymddiriedolaeth GIG Gwasanaethau Ambiwllans Cymru*”) means the Welsh Ambulance Services National Health Service Trust(**13**);

“Welsh care home” (“*cartref gofal yng Nghymru*”) means [<sup>F6</sup>a place at which a care home service, within the meaning of Part 1 of the Regulation and Inspection of Social Care (Wales) Act 2016, is provided wholly or mainly to persons aged 18 or over];

“Welsh independent hospital” (“*ysbyty annibynnol yng Nghymru*”) means a body that runs a hospital in Wales which is not a health service hospital (within the meaning given in section 206(1) of the NHS (Wales) Act 2006 (interpretation and construction)) but which is—

- (a) an establishment, the main purpose of which is to provide palliative care or medical or psychiatric treatment for illness or for mental disorder (that is, mental illness, arrested or incomplete development of mind, psychopathic disorder, or any other disorder or disability of mind); or
- (b) any other establishment in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983(**14**).

(2) Where, by virtue of these Regulations, a person or body is required to ensure a matter, the requirement is to be construed as a requirement to take all reasonable steps to ensure that matter.

(3) Where the reference is made in these Regulations to arrangements to provide services, the reference is to be construed as a reference to arrangements to provide services that involve, or may involve, the management or use of controlled drugs.

(4) For the purposes of these Regulations, “enactment” (“*deddfiad*”) includes, an enactment comprised in, or an instrument made under, a Measure [<sup>F7</sup>or an Act] of the National Assembly for Wales.

- F1** Words in [reg. 2\(1\)](#) omitted (31.12.2020) by virtue of [The Retained EU Law \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1281), [regs. 1\(2\), 7\(2\)\(a\)](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F2** Words in [reg. 2\(1\)](#) substituted (6.4.2016) by [The Social Services and Well-being \(Wales\) Act 2014 \(Consequential Amendments\) \(Secondary Legislation\) Regulations 2016](#) (S.I. 2016/211), [reg. 1\(2\), Sch. 3 para. 107](#)
- F3** Words in [reg. 2](#) substituted (27.9.2010) by [The Pharmacy Order 2010](#) (S.I. 2010/231), [art. 1\(5\), Sch. 4 para. 68\(a\)](#) (with [Sch. 5](#)); S.I. 2010/1621, [art. 2\(1\), Sch.](#)
- F4** Words in [reg. 2](#) substituted (27.9.2010) by [The Pharmacy Order 2010](#) (S.I. 2010/231), [art. 1\(5\), Sch. 4 para. 68\(b\)](#) (with [Sch. 5](#)); S.I. 2010/1621, [art. 2\(1\), Sch.](#)
- F5** Words in [reg. 2\(1\)](#) inserted (31.12.2020) by [The Retained EU Law \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/1281), [regs. 1\(2\), 7\(2\)\(b\)](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F6** Words in [reg. 2\(1\)](#) substituted (2.4.2018) by [The Regulation and Inspection of Social Care \(Wales\) Act 2016 \(Consequential Amendments to Secondary Legislation\) Regulations 2018](#) (S.I. 2018/48), [reg. 1\(2\), Sch. 1 para. 19\(2\)](#)
- F7** Words in [reg. 2\(4\)](#) inserted (5.5.2011) by [The Government of Wales Act 2006 \(Commencement of Assembly Act Provisions, Transitional and Saving Provisions and Modifications\) Order 2011](#) (S.I. 2011/1011), [arts. 2, 8](#)

#### Commencement Information

- I2** Reg. 2 in force at 9.1.2009, see [reg. 1\(2\)](#)

(13) Established by S.I. 1998/678.

(14) 1983 c. 20.

**Changes to legislation:**

There are currently no known outstanding effects for the The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008, PART 1.