Changes to legislation: *There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

WELSH STATUTORY INSTRUMENTS

2008 No. 3239 (W.286)

DANGEROUS DRUGS, WALES

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

Made - - - -	*16 December 2008*
Laid before the National Assembly for Wales - -	*18 December 2008*
Coming into force - -	*9 January 2009*

The Welsh Ministers, in exercise of the powers conferred by sections 17, 18, 20(3) and (7) and 79(3) of the Health Act 2006(**1**), make the following Regulations:

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

I1 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(**2**);

(**1**) 2006 c. 28. The powers of the National Assembly for Wales under sections 17, 18, 20 and 79 of the Health Act 2006 were transferred to the Welsh Ministers in accordance with paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).

(**2**) 2000 c. 14.

"the 2003 Act" ("*Deddf 2003*") means the Health and Social Care (Community Health and Standards) Act 2003(**3**);

"the 2006 Act" ("*Deddf 2006.*") means the Health Act 2006(**4**);

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

"CSSIW" ("*AGGCC*") means the Care and Social Services Inspectorate for Wales(**5**);

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

"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;

"HIW" ("*AGIC*") means the Healthcare Inspectorate for Wales(**6**);

"the health service" ("*y gwasanaeth iechyd*") means the health service established in pursuance of the National Health Service Act 1946(**7**);

"local authority" ("*awdurdod lleol*") means a Welsh council referred to in section 1 of the Local Authority Social Services Act 1970(**8**) (local authorities);

"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(**9**);

"misuse of drugs legislation" ("*deddfwriaeth am gamddefnyddio cyffuriau*") means the Misuse of Drugs Act 1971(**10**) 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(**11**);

"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(**12**) (the dentists register and registrar);

"registered pharmacist" ("*fferyllydd cofrestredig*") means a person registered in the register of pharmacists maintained by the Royal Pharmaceutical Society of Great Britain;

"retail pharmacy business" ("*busnes manwerthu fferyllol*") has the meaning given in section 132 of the Medicines Act 1968(**13**) (registration of premises);

(**3**) 2003 c. 43.
(**4**) 2006 c. 28.
(**5**) 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.
(**6**) The Healthcare Inspectorate Wales ("HIW") is an operationally distinct division of the Department of Public Services and Performance within the Welsh Assembly Government.
(**7**) 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").
(**8**) 1970 c. 42; amended by the Local Government Act 1972 (c. 70), section 195(3), and the Local Government (Wales) Act 1994 (c. 19), Schedule 10, paragraph 7.
(**9**) 2006 c. 42.
(**10**) 1971 c. 38.
(**11**) S.I.2005/3361
(**12**) 1984 c. 24.
(**13**) 1968 c. 67. There are amendments to section 132 which are not relevant to the definition of "retail pharmacy business".

"registered pharmacy" ("*fferyllfa gofrestredig*.") means a retail pharmacy business in Wales that it for the time being entered in the register kept under section 75 of the Medicines Act 1968 (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)(**14**);

"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;

"Welsh Ambulance Services NHS Trust ("*Ymddiriedolaeth GIG Gwasanaethau Ambiwlans Cymru*") means the Welsh Ambulance Services National Health Service Trust(**15**);

"Welsh care home" ("*cartref gofal yng Nghymru*") means a body that runs an establishment in Wales which is a care home for the purposes of the 2000 Act by virtue of section 3 of that Act (care homes);

"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(**16**).

(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 of the National Assembly for Wales.

Commencement Information

I2 Reg. 2 in force at 9.1.2009, see **reg. 1(2)**

PART 2

Accountable Officers

Designated bodies

3. The following are prescribed as designated bodies for the purposes of section 17 of the 2006 Act—

(a) a Local Health Board;

(**14**) 2002 c. 17.
(**15**) Established by S.I. 1998/678.
(**16**) 1983 c. 20.

(b) an NHS Trust;

(c) the Welsh Ambulance Services NHS Trust;

(d) a Welsh independent hospital.

Commencement Information

I3 Reg. 3 in force at 9.1.2009, see **reg. 1(2)**

Appointment of accountable officers and national lists

4.—(1) A designated body must nominate or appoint (or under regulation 5(2) or (4) jointly nominate or appoint with one or more other bodies) a fit and proper suitably experienced person as its accountable officer.

(2) A designated body must notify the Chief Executive of HIW in writing—

(a) any nomination or appointment by it in under paragraph (1) as soon as practicable; and

(b) the removal of an accountable officer by it (whether or not under regulation 6) as soon as practicable.

(3) HIW must publish, from time to time and in such manner as it sees fit, a list of accountable officers of designated bodies in Wales.

Commencement Information

I4 Reg. 4 in force at 9.1.2009, see **reg. 1(2)**

Persons who may be appointed as accountable officers

5.—(1) A Welsh independent hospital may only nominate or appoint a person as its accountable officer if—

(a) the person is—

(i) its registered manager, or

(ii) one of its officers or employees who is answerable to its registered manager,

and if the person is its registered manager, he or she must be answerable to the chief executive, chairman or managing director of the hospital; and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his or her duties.

(2) Two or more Welsh independent hospitals may jointly nominate or appoint one registered manager to be the accountable officer for both or all of the hospitals if the registered manager—

(a) is registered as manager in relation to both or all of the hospitals; and

(b) does not routinely supply, administer or dispose of controlled drugs as part of his or her duties.

(3) Subject to paragraph (4), a designated body specified in regulation 3(a), (b) or (c) may only nominate or appoint a person as its accountable officer if—

(a) the person is an officer or employee of the designated body, and—

(i) a member of the board of directors, or the management or executive committee of the designated body,

(ii) a member of the body (howsoever it may be called) that has responsibility for the management of the designated body, or

(iii) is answerable to a person referred to in paragraph (i) or (ii); and

(b) the person does not routinely supply, administer or dispose of controlled drugs as part of his or her duties.

(4) Two or more designated bodies specified in regulation 3(a), (b) or (c) but which are of the same type may jointly nominate or appoint one person to be the accountable officer for both or all of the bodies, if—

(a) the person satisfies paragraph (3)(a) in relation to one of the designated bodies;

(b) each designated body is satisfied that the person can properly discharge his or her responsibilities in relation to it; and

(c) the person does not routinely supply, administer or dispose of controlled drugs as part of his or her duties.

(5) In this regulation "registered manager" ("*rheolwr cofrestredig*"), in relation to a Welsh independent hospital, means the person who is registered under Part II of the 2000 Act as the manager of the hospital.

Commencement Information

I5 Reg. 5 in force at 9.1.2009, see **reg. 1(2)**

Removal of accountable officers

6.—(1) A designated body must, having duly considered the matter, remove its accountable officer if the accountable officer—

(a) no longer satisfies the conditions set out in regulation 5; or

(b) is unfit to be an accountable officer.

(2) A designated body (or, in the case of a joint appointment, the designated bodies that made the joint appointment, acting jointly) must adopt a procedure (which may be part of an internal disciplinary procedure) for consideration, where it is on notice that its accountable officer has breached his or her duties under these Regulations, of whether or not it needs to remove its accountable officer under paragraph (1)(b).

(3) A person will be presumed (unless the contrary is proved) to be unfit to be an accountable officer if he or she wilfully, negligently or through lack of competence breaches his or her duties as an accountable officer under these Regulations.

(4) This regulation is without prejudice to any other arrangements that a designated body (or, in the case of a joint appointment, the designated bodies that made the joint appointment, acting jointly) may have for removal of its accountable officer from office as part of the arrangements under which he or she is employed or engaged.

Commencement Information

I6 Reg. 6 in force at 9.1.2009, see **reg. 1(2)**