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.

Interpretation

2.—(1) In these Regulations—

"the 2000 Act" ("*Deddf 2000*") means the Care Standards Act 2000(**2**);

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

(**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.
(**3**) 2003 c. 43.

"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);

"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);

(**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".

"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.

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;

(b) an NHS Trust;

(c) the Welsh Ambulance Services NHS Trust;

(d) a Welsh independent hospital.

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

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.

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.

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.

Funds and other resources available to accountable officers

7.—(1) A designated body must provide its accountable officer with the funds and other resources necessary to enable the accountable officer to carry out his or her responsibilities as its accountable officer.

(2) Those other resources may include access to and use of information systems, accommodation and staff.

Accountable officers to have regard to best practice

8. In discharging his or her responsibilities, an accountable officer must have regard to best practice in relation to the management and use of controlled drugs.

Accountable officers to secure the safe management and use of controlled drugs

9.—(1) An accountable officer must—

(a) both—

(i) establish and operate, or ensure, that his or her designated body establishes and operates, appropriate arrangements for securing the safe management and use of controlled drugs by the designated body, and

(ii) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his or her designated body establishes and operates appropriate arrangements for securing the safe management and use of controlled drugs by that body or person; and

(b) both—

(i) review, or ensure that his or her designated body reviews, arrangements established by the accountable officer or his or her designated body,

(ii) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his or her designated body reviews arrangements established by it or the accountable officer in accordance with sub-paragraph (a)(ii).

(2) In particular, an accountable officer must, as part of these arrangements—

(a) establish or ensure that his or her designated body (and any body or person acting on behalf of, or providing services under arrangements made with, his or her designated body) establishes appropriate arrangements to comply with the misuse of drugs legislation; and

(b) ensure that his or her designated body (and any body or person acting on behalf of, or providing services under arrangements made with, his or her designated body) has adequate and up-to-date standard operating procedures in place in relation to the management and use of controlled drugs.

(3) The standard operating procedures must, in particular, cover the following matters—

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as required by the misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including—

(i) maintaining relevant controlled drugs registers under the misuse of drugs legislation, and

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2001(**17**) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

Accountable officers to ensure adequate destruction and disposal arrangements for controlled drugs

10. An accountable officer must—

(a) establish and operate, or ensure that his or her designated body establishes and operates appropriate arrangements for securing the safe destruction and disposal of controlled drugs by his or her designated body, and

(b) ensure that any body or person acting on behalf of, or providing services under arrangements made with, his or her designated body establishes and operates appropriate arrangements for securing the safe destruction and disposal of controlled drugs by that body or person.

Accountable officers to ensure monitoring and auditing of the management and use of controlled drugs by designated bodies etc.

11.—(1) An accountable officer must——

(a) establish and operate, or ensure that his or her designated body establishes and operates, appropriate arrangements for monitoring and auditing the designated body's management and use of controlled drugs; and

(b) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his or designated body establishes and operates appropriate arrangements for

(**17**) S.I. 2001/3998; the relevant amending instrument is 2003/1432.

monitoring and auditing the person or body's management and use of controlled drugs (that is, their management and use of controlled drugs under their arrangements with the designated body, not under any other arrangements).

(2) Those arrangements must, in particular, provide for the following—

(a) monitoring and analysing health service and private prescribing of controlled drugs through the use of data relating to the prescribing and dispensing of prescriptions in Wales available from Health Solutions Wales.

(b) ensuring that the designated body (and any body or person acting on behalf of, or providing services under arrangements made with, the designated body) has systems in place to alert the accountable officer of any complaints or concerns involving the management or use of controlled drugs;

(c) ensuring that the designated body (and any body or person acting on behalf of, or providing services under arrangements made with, the designated body) has an incident reporting system in place for untoward incidents involving the management or use of controlled drugs; and

(d) ensuring that the designated body (and any body or person acting on behalf of, or providing services under arrangements made with, the designated body) has appropriate arrangements in place for analysing and responding to untoward incidents involving the management or use of controlled drugs.

Powers to require declarations and self-assessments, as part of accountable officers' monitoring and auditing arrangements or otherwise

12.—(1) An accountable officer, who is an accountable officer nominated or appointed by a Local Health Board, may request a periodic declaration and a self-assessment from a general medical practitioner on its medical performers list, which must state

(a) whether the practitioner uses controlled drugs at any of the premises from which he or she provides primary medical services as part of the health service; and

(b) how the practitioner manages and uses controlled drugs at those premises.

(2) HIW may request an appropriate periodic declaration and an appropriate self-assessment from an NHS trust or a person registered with them that provides health care.

(3) CSSIW may request an appropriate periodic declaration and an appropriate self-assessment from a Welsh care home.

(4) The Royal Pharmaceutical Society of Great Britain may request an appropriate periodic declaration and an appropriate self-assessment from a registered pharmacy.

(5) In this regulation, "general medical practitioner" ("*ymarferydd meddygol cyffredinol*") means a medical practitioner whose name is included in the register maintained by the General Medical Council under article 10 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 (the General Practitioner Register(**18**)).

Accountable officers to ensure relevant individuals receive appropriate training etc.

13.—(1) An accountable officer must—

(a) establish and operate, or ensure that his or her designated body establishes and operates; and

(b) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his or her designated body establishes and operates,

(**18**) S.I. 2003/1250.

the arrangements mentioned in paragraph (2).

(2) Those arrangements are appropriate arrangements to ensure that persons who are—

(a) as regards the designated body, relevant individuals(**19**); and

(b) involved in prescribing, supplying, administering or disposing of controlled drugs,

receive, from time to time, appropriate training to carry out their responsibilities.

(3) The accountable officer must liaise with his or her designated body to ensure that arrangements are in place for the relevant individuals referred to in paragraph (2)—

(a) to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs; and

(b) to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended.

Accountable officers to monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance

14.—(1) An accountable officer must—

(a) establish and operate, or ensure that his or her designated body establishes and operates; and

(b) ensure that a body or person acting on behalf of, or providing services under arrangements made with, his or her designated body establishes and operates,

the arrangements mentioned in paragraph (2).

(2) Those arrangements are appropriate arrangements—

(a) for monitoring and auditing the management and use of controlled drugs by a person who is, as regards the designated body, a relevant individual; and

(b) for monitoring and assessing the performance of persons who are, as regards the designated body, relevant individuals, in connection with the management and use of controlled drugs.

(3) The arrangements under paragraph (1) must, where appropriate, provide for the following—

(a) recording, in accordance with regulation 15, any concerns raised in relation to the management or use of controlled drugs by a relevant individual;

(b) assessing and investigating, in accordance with regulation 16, any concerns raised regarding the management or use of controlled drugs by a relevant individual; and

(c) determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body under regulation 25.

Accountable officers to maintain a record of concerns regarding relevant individuals

15.—(1) An accountable officer must—

(a) establish and operate, or ensure that his or her designated body establishes and operates, appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his or her designated body, a relevant individual; and

(b) ensure that any body or person acting on behalf of, or providing services under arrangements made with, his or her designated body establishes and operates appropriate

(**19**) The expression "*relevant individual*" is defined in section 17(8)(b) of the Health Act 2006

arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his or her designated body, a relevant individual.

(2) The accountable officer must ensure, as part of the arrangements under paragraph (1), that adequate records are compiled, which must include (but not be limited to), as appropriate——

(a) the date on which the concern was made known to the accountable officer;

(b) any dates on which the matters that led to the concern took place;

(c) details regarding the nature of the concern;

(d) details of the relevant individual in relation to whom the concern was expressed;

(e) details of the person who, or body which, made known the concern;

(f) details of any action taken by the designated body (or a body or person acting on behalf of, or providing services under arrangements made with, the designated body) in relation to the concern;

(g) the assessment of whether information in relation to the concern should be disclosed to another responsible body under regulation 25 or 26; and

(h) if information regarding the concern is disclosed to another responsible body under regulation 25 or 26, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

(3) Any record of a concern may be kept in paper or electronic format.

(4) The arrangements under paragraph (1) must include arrangements that limit access to the records to—

(a) the accountable officer and his or her staff; and

(b) others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.

Accountable officers to assess and investigate concerns

16.—(1) An accountable officer must establish and operate, or ensure that his or her designated body establishes and operates, appropriate arrangements for—

(a) assessing concerns expressed about incidents that involved, or may have involved, the improper management or use of controlled drugs by a person who is, as regards his or her designated body, a relevant individual; and

(b) investigating such concerns.

(2) If, after an assessment of a concern expressed, the accountable officer decides that an investigation is needed, the accountable officer may—

(a) carry out that investigation personally;

(b) make a written request for another officer or employee of his or her designated body to carry out the investigation; or

(c) if appropriate, and subject to paragraphs (5) and (6)——

(i) make a written request for an officer or employee (including, in the case of a designated body, an accountable officer) from any of the responsible bodies listed in paragraph (3) to carry out the investigation, or

(ii) make a written request for a number of officers or employees from any of the responsible bodies listed in paragraph (3) to form a joint investigation team to carry out the investigation.

(3) The following are responsible bodies for the purposes of section 18 of the 2006 Act and this regulation—

(a) a designated body;

(b) HIW;

(c) the Counter Fraud and Security Management Service Division of the NHS Business Services Authority;

(d) CSSIW;

(e) a police force;

(f) a regulatory body.

(4) An accountable officer may use his or her powers under paragraph (2)(c) to request an investigation (or a joint investigation with other responsible bodies) by the Counter Fraud and Security Management Service Division of the NHS Business Services Authority into any possible fraud in relation to the health service.

(5) The accountable officer must keep, or ensure that his or her designated body keeps, a record of——

(a) any request made to an accountable officer from another designated body, or to another responsible body, under paragraph (2)(c) to investigate a concern that involved, or may have involved, the improper management or use of controlled drugs;

(b) any assessment or investigation of a concern that involved, or may have involved, improper management or use of controlled drugs by a relevant individual that the accountable officer or his or her designated body carried out; and

(c) any notification given to another responsible body or accountable officer under regulation 25(4).

Accountable officers to take appropriate action if there are well-founded concerns

17.—(1) An accountable officer must establish and operate, or ensure that his or her designated body establishes and operates, appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards the designated body, a relevant individual, appear to be well-founded.

(2) If there are well-founded concerns in relation to the management or use of controlled drugs by relevant individuals, or wider concerns of possible fraud in relation to the health service, as part of the arrangements established under paragraph (1), but subject to paragraphs (4) and (5), the action that the accountable officer may take may include (although it need not be limited to) any of the following—

(a) requesting additional advice, support, mentoring or training from an appropriate person, including—

(i) a prescribing advisor,

(ii) a clinical governance lead, or

(iii) in the case of an employee, a line manager within the designated body;

(b) implementation of a serious untoward incident procedure;

(c) referral of the concerns to a regulatory body;

(d) referral of the concerns to a police force;

(e) in a case of possible fraud in relation to the health service, referral of the concerns to the Counter Fraud and Security Management Service Division of the NHS Business Services Authority;

(f) sharing information with, and requesting information from, other responsible bodies, in accordance with regulation 25 or 26; or

(g) if the accountable officer is an accountable officer nominated or appointed by a Local Health Board, convening an incident panel, made up of officers from any of the bodies that are responsible bodies for the purposes of Part 4, to investigate the concern and make recommendations as mentioned in paragraph (3).

(3) An incident panel convened under paragraph (2)(g) may recommend that the accountable officer or designated body take action that includes (although it need not be limited to) any of the following—

(a) ongoing monitoring of the relevant individual;

(b) referral of the concerns to another accountable officer;

(c) referral of the concerns to a regulatory body;

(d) referral of the concerns to a police force; or

(e) implementation of a serious untoward incident procedure.

Accountable officers to establish arrangements for sharing information

18.—(1) An accountable officer must establish and operate, or ensure that his or her designated body establishes and operates, appropriate arrangements for ensuring the proper sharing of information, in accordance with regulation 25 or 26, by his or her designated body with other responsible bodies regarding the management and use of controlled drugs.

(2) If the accountable officer is an accountable officer nominated or appointed by Local Health Board, those arrangements must include establishing a network (a "local intelligence network") for sharing information regarding the management and use of controlled drugs.

(3) The network must include (although it need not be limited to) the following types of bodies, as appropriate—

(a) a Local Health Board;

(b) an NHS trust;

(c) HIW;

(d) CSSIW;

(e) the Counter Fraud and Security Management Service Division of the NHS Business Services Authority;

(f) a regulatory body;

(g) a police force; and

(h) a local authority.

PART 3

Entering premises, periodic inspections etc.

Accountable officers to carry out periodic inspections

19.—(1) An accountable officer, who is an accountable officer nominated or appointed by a Local Health Board, must establish and operate appropriate arrangements or ensure that his or her designated body establishes and operates appropriate arrangements for making, in connection with the performance of functions under these Regulations, periodic inspections (in accordance with section 20 of the 2006 Act) of premises which are—

(a) used in connection with management or use of controlled drugs; and

(b) not subject to inspection by—

(i) HIW,

(ii) CSSIW, or

(iii) the Royal Pharmaceutical Society of Great Britain.

(2) Where a designated body has authorised in writing under section 20(5)(c) of the 2006 Act a person to carry out inspections of relevant premises (or of specific relevant premises), the arrangements under paragraph (1) may (where appropriate) provide for that person to carry out periodic inspections under the arrangements.

(3) The accountable officer, or the person referred to in paragraph (2), is not required to give notice of the inspection to the owner or occupier of the premises.

(4) The accountable officer, or the person referred to in paragraph (2), must keep a record of all the inspections carried out by him or her as part of the arrangements made under paragraph (1).

(5) That record of inspections may be kept in paper or electronic format.

Relevant premises

20.—(1) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer who is an accountable officer nominated or appointed by a Local Health Board or (where appropriate) by a member of the staff of the Local Health Board——

(a) the premises of the Local Health Board for which he or she is the accountable officer or (where appropriate) of which he or she is a member of staff;

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with, that Local Health Board, unless those arrangements are with an NHS trust or a Welsh independent hospital; and

(c) any other premises which are covered by arrangements established by virtue of regulation 19(1) but which are not mentioned in sub-paragraphs (a) or (b).

(2) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer who is an accountable officer nominated or appointed by an NHS trust or (where appropriate) by a member of the staff of the NHS trust—

(a) the premises of the NHS trust for which he or she is the accountable officer or (where appropriate) of which he or she is a member of staff; and

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with, that NHS trust, unless those arrangements are with a Local Health Board or a Welsh independent hospital.

(3) For the purposes of section 20 of the 2006 Act, the following are prescribed as relevant premises which may be inspected by an accountable officer who is an accountable officer nominated or appointed by a Welsh independent hospital or (where appropriate) by a member of the staff of the independent hospital——

(a) the premises of the independent hospital for which he or she is the accountable officer; and

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with, that independent hospital, unless those arrangements are with a Local Health Board or an NHS trust.

(4) All the premises mentioned in paragraphs (1) to (3) are also prescribed as relevant premises in relation to constables and persons authorised by the relevant authority under section 20(5)(a) of the 2006 Act (and accordingly they may exercise the powers under section 20 of the 2006 Act as regards those premises).

(5) An authorisation given under section 20(5)(a) or (c) of the 2006 Act must be in writing.

(6) An accountable officer ("the first accountable officer") may request in writing that an accountable officer of another designated body of the same type inspect—

(a) the premises of the designated body of the first accountable officer; or

(b) the premises of a body or person acting on behalf of, or providing services under arrangements made with the designated body of the first accountable officer,

subject to an appropriate authorisation being granted.

Inspections of private dwellings not requiring the presence of a constable

21. Section 20(3) of the 2006 Act does not apply as regards—

(a) a member of staff of, or person authorised by, CSSIW entering a Welsh care home;

(b) an officer of the Royal Pharmaceutical Society of Great Britain entering a registered pharmacy;

(c) a member of staff of, or a person authorised by, a designated body, entering premises which are or form part of a private dwelling of a health care professional—-

(i) who is providing health care (which includes the services of a pharmacist) at the private dwelling, and

(ii) the private dwelling is on a statutory register of health care premises or is designated as practice premises under arrangements with a Local Health Board to provide primary medical or dental services.

PART 4

Co-operation between health bodies and other organisations

Responsible bodies for the purposes of this Part

22.—(1) The following are responsible bodies for the purposes of section 18 of the 2006 Act and this Part—

(a) a Local Health Board;

(b) an NHS trust;

(c) the Welsh Ambulance Services NHS Trust;

(d) a Welsh independent hospital;

(e) HIW;

(f) CSSIW;

(g) the NHS Business Services Authority, in relation to the performance of its functions by the Counter Fraud and Security Management Service Division;

(h) Health Solutions Wales

(i) a police force;

(j) a local authority; and

(k) a regulatory body.

Relevant persons

23. In accordance with section 19(1)(a) of the 2006 Act, the following are prescribed as relevant persons (and accordingly are "relevant persons" for the purposes of this Part in addition to those persons who are mentioned in section 19(1)(b) of the 2006 Act)—

(a) a registered medical practitioner or registered dentist who is providing medical services to private patients only;

(b) a person engaged in any activity carried on by a registered medical practitioner or registered dentist referred to in paragraph (a) that involves, or may involve, the supply or administration of controlled drugs;

(c) a registered pharmacist who is providing services on behalf of, or under arrangements made with, a registered pharmacy, in circumstances where that registered pharmacy is not providing services as part of the health service (whether under arrangements made with a designated body or on behalf of a person or body that has such arrangements);

(d) a person, other than a registered pharmacist, engaged in any activity carried on or by a registered pharmacist referred to in paragraph (c) that involves, or may involve the supply or administration of controlled drugs;

(e) a registered midwife or nurse who is providing midwifery or nursing services to private patients only that involve, or may involve, the supply or administration of controlled drugs;

(f) a person who is carrying on or engaged in any activity that involves, or may involve, the supply or administration of controlled drugs, and who is——

(i) a person who is registered under Part II of the 2000 Act as the manager of, or the person who is carrying on, a care home (referred to in this paragraph as "a registered person"), or

(ii) a person engaged in any activity carried on by a registered person.

General duty on responsible bodies to co-operate with each other as regards relevant persons

24. Responsible bodies must co-operate with each other in connection with—

(a) the identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person;

(b) the consideration of issues relating to the taking of action in respect of such matters; and

(c) the taking of action in respect of such matters.

Duty to co-operate by disclosing information as regards relevant persons

25.—(1) A responsible body may disclose to any other responsible body any information in its possession or control which it reasonably considers it should share with that body for the purposes of—

(a) identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person;

(b) the consideration of issues relating to the taking of action in respect of such matters;

(c) the taking of action in respect of such matters.

(2) If the responsible body wishes to disclose information under this regulation which—

(a) contains confidential information which relates to and can identify a patient; and

(b) that confidential information is not required for the purposes of identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person, or for considering or taking action in such a case,

the responsible body must, so far as it is practical to do so, remove from the information the confidential information which relates to and can identify the patient.

(3) If the responsible body—

(a) is unable, under paragraph (2), to remove from any information to be disclosed any confidential information which relates to and can identify a patient; or

(b) considers it necessary to disclose information which contains the confidential information that relates to and can identify the patient,

the responsible body must, where practicable, obtain the consent of the patient to whom the information relates.

(4) If the responsible body (or its accountable officer) has—

(a) commenced an assessment of or an investigation into a matter of concern in relation to the management or use of controlled drugs by a relevant individual under regulation 16 (that individual being a relevant person for the purposes of this Part); or

(b) completed an assessment of or an investigation into a matter of concern under regulation 16,

it must notify the persons and bodies listed in paragraph (5) of the commencement or completion of the assessment or investigation, as the case may be, and provide appropriate details regarding the nature of the assessment or investigation.

(5) Those persons and bodies are—

(a) if the responsible body has an accountable officer and he or she is unaware of the action taken, that accountable officer;

(b) the accountable officer nominated or appointed as accountable officer for any Local Health Board in whose area the relevant individual lives or provides health care or services related to health care; and

(c) any other responsible body that it considers it appropriate to notify.

(6) A responsible body is not required to notify any person or body, or to provide any details, under paragraph (4) where to do so would prejudice or would be likely to prejudice—

(a) any investigation being conducted by the responsible body, or any other responsible body, under any enactment; or

(b) any civil or criminal proceedings.

(7) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

(8) In determining for the purposes of paragraph (7) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998 by virtue of section 35(1) of that Act (disclosure required by law or

made in connection with legal proceedings etc), it is to be assumed that the disclosure is required by this regulation.

Responsible bodies requesting additional information be disclosed about relevant persons

26.—(1) If a responsible body has in its possession or control information relating to the management or use of controlled drugs by a relevant person that it considers to be of serious concern (which may be fitness to practise information that is unrelated to any specific instance of the management or use of a controlled drug), it may request in writing additional information in relation to the matter from any other responsible body which it considers may have relevant information.

(2) If a responsible body has received a request under paragraph (1)—

(a) it must determine within a reasonable period of time whether or not to comply with the request; and

(b) it may disclose any information relating to the management or use of controlled drugs by a relevant person which it reasonably considers to be relevant to the request.

(3) If the responsible body wishes to disclose information under this regulation which contains confidential information which relates to and can identify a patient, the responsible body must, so far as it is practical to do so, remove from the information the confidential information which relates to and can identify the patient.

(4) If the responsible body—

(a) is unable, under paragraph (3), to remove from any information to be disclosed any confidential information which relates to and can identify a patient; or

(b) considers it necessary to disclose information which contains the confidential information that relates to and can identify the patient,

the responsible body must, where practicable, obtain the consent of the patient to whom the information relates.

(5) A responsible body is not required to disclose information under this regulation if the disclosure—

(a) would prejudice, or would be likely to prejudice, any investigation being conducted by the responsible body, or by any other responsible body, under any enactment;

(b) would prejudice, or would be likely to prejudice, any civil or criminal proceedings; or

(c) would involve disproportionate cost.

(6) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

(7) In determining for the purposes of paragraph (6) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998 by virtue of section 35(1) of that Act (disclosure required by law or made in connection with legal proceedings etc.), it is to be assumed that the disclosure is required by this regulation.

Restrictions relating to disclosures

27.—(1) If a responsible body that is disclosing or to which is being disclosed any information under regulation 25 or 26 has an accountable officer, the disclosure must be made by or to the accountable officer or his or her staff (and not by or to any other person who may act on behalf of the responsible body).

(2) If a responsible body has received information under regulation 25 or 26, it must not process that information more than is necessary for the purposes of—

(a) identifying cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by a relevant person;

(b) considering issues relating to the taking of action in respect of such matters; or

(c) taking action in respect of such matters.

(3) In particular, the responsible body must—

(a) not allow any person access to that information unless he or she is a person who, by virtue of his or her contract of employment or otherwise, is aware of the purposes for which the information may be processed; and

(b) ensure that appropriate organisational measures are taken to prevent unauthorised disclosure or processing of the information.

Record keeping requirements relating to regulations 25 and 26

28.—(1) A responsible body must keep a record of—

(a) a decision to disclose information under regulation 25;

(b) details of the nature of the information disclosed;

(c) details of the responsible body to which information was disclosed; and

(d) any other details which the responsible body considers to be relevant to the disclosure.

(2) A responsible body must keep a record of—

(a) any request received from another responsible body to disclose information under regulation 26;

(b) details of the nature of any information disclosed;

(c) details of the responsible body to which the information was disclosed; and

(d) any other details which the responsible body considers to be relevant to the disclosure.

(3) The records may be kept in paper or electronic format.

Occurrence reports

29.—(1) An accountable officer (other than an accountable officer nominated or appointed as accountable officer for a Local Health Board) must give, on a quarterly basis, an occurrence report to the accountable officer nominated or appointed as accountable officer for the Local Health Board that is leading any local intelligence network of which he or she or his or her designated body is a member.

(2) The occurrence report may contain the following information——

(a) details of any concerns that his or her designated body has regarding its management or use of controlled drugs; or

(b) confirmation by his or her designated body that it has no concerns to report regarding its management or use of controlled drugs.

(3) Nothing in this regulation requires or permits any disclosure of information which is prohibited by or under any other enactment.

(4) In determining for the purposes of paragraph (3) whether disclosure is not prohibited by reason of being a disclosure of personal data which is exempt from the non-disclosure provisions of the Data Protection Act 1998 by virtue of section 35(1) of that Act (disclosure required by law or made in connection with legal proceedings etc), it is to be assumed that the disclosure is required by this regulation.

Accountable officers' duties to protect the safety of patients and the general public

30.—(1) If the information shared by a responsible body under regulation 25 or 26 shows a concern about inappropriate or unsafe use of controlled drugs by a relevant person, the accountable officer of any designated body responsible for—

(a) entering into any arrangements with the relevant person; or

(b) entering into any arrangements with any other person or body, under which the relevant person provides or may provide services,

that has possession or control of that information may make recommendations to any responsible body (including, where appropriate, his or her own designated body) as to any action which the accountable officer considers that the responsible body should take to protect the safety of patients or the general public.

(2) If the concern relates to a relevant person who is not providing services to, or under arrangements that another person or body has with, a designated body, the accountable officer leading the local intelligence network for any area in which the relevant person lives or provides services must—

(a) seek to take reasonable steps to protect the safety of patients or the general public; and

(b) where appropriate, refer the matter to a relevant responsible body (for example, a regulatory body or a police force).

Disclosure of information in good faith

31. Civil proceedings do not lie against a person in respect of loss, damage or injury of any kind suffered by another person as a result of the disclosure of information in good faith under regulation 25, 26, 29 or 30.

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

16 December 2008

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations contain measures relating to arrangements underpinning the safe management and use of controlled drugs in Wales.

Part 1 outlines preliminary matters.

Part 2 relates to accountable officers. A number of health care bodies are prescribed as designated bodies (regulation 3), and these are required to appoint accountable officers (regulation 4). There are limitations upon who may act as accountable officers (regulation 5) and a duty on designated bodies to establish arrangements for their removal from office in specified circumstances (regulation 6). Designated bodies are required to ensure that their accountable officers have sufficient resources available to them (regulation 7).

Accountable officers are given a number of functions relating to the safe management and use of controlled drugs. Essentially, these require the establishment by the accountable officer of a number of sets of arrangements which relate to the safe management and use of controlled drugs. As well as the basic arrangements (regulation 9), these include safe disposal arrangements (regulation 10) and auditing arrangements (regulation 11). As well as being given functions in relation to their own designated bodies, accountable officers are given functions in relation to health care professionals and others whose work involves the management and use of controlled drugs, for which their designated body is responsible. These responsibilities include maintaining records of and investigating concerns (regulations 15 and 16), and taking appropriate action where there are well-founded concerns (regulation 17). Accountable officers for Local Health Boards also have particular responsibilities for setting up local intelligence networks, relating to the management and use of controlled drugs, for their area (regulation 18).

Part 3 contains arrangements in relation to periodic inspections of premises used for the management and use of controlled drugs, where these issues would not be dealt with as part of other health and social care inspections, and other measures in relation to powers of entry.

Part 4 deals with co-operation between a number of listed health care bodies and other organisations (regulation 22), and in particular, contains detailed arrangements with regards to the disclosure of information between the bodies that are required, by the Regulations, to co-operate with each other in connection with the identification of cases where action may need to be taken against individuals (regulations 24 to 27). There are record keeping requirements (regulation 28), and duties with regard to occurrence reports, which are quarterly statements that accountable officers must make about details of concerns that their designated body has (regulation 29). Accountable officers have duties to take action with regard to concerns that they have (regulation 30), and persons acting in good faith under the arrangements for sharing information under this Part are protected from damages claims (regulation 31).