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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 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.

**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<sup>(1)</sup> (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 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.

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

### **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<sup>(2)</sup>).

### **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,

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<sup>(3)</sup>; 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—

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(2) S.I. 2003/1250.

(3) The expression “*relevant individual*” is defined in section 17(8)(b) of the Health Act 2006

- (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 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.