WELSH STATUTORY INSTRUMENTS

2008 No. 3239

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

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.