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WELSH STATUTORY INSTRUMENTS

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**2011 No. 734**

**The Independent Health Care (Wales) Regulations 2011**

**PART III**

Conduct of Health Care Establishments and Agencies

Chapter 1

Quality of Service Provision

**Quality of treatment and other service provision**

**15.**—(1) Subject to regulation 6(4), the registered person must provide any treatments and other services to patients in accordance with the statement of purpose, and must ensure that any treatments and other services provided to each patient—

- (a) meet the patient's individual needs;
- (b) ensure the welfare and safety of the patient;
- (c) are evidence based; and
- (d) are (where necessary) provided by means of appropriate equipment.

(2) The registered person must ensure that all equipment used in or for the purposes of the establishment or for the purposes of the agency is safe and in good condition and suitable for the purpose it is to be used for.

(3) Where reusable medical devices are used in an establishment or for the purposes of an agency, the registered person must ensure that appropriate procedures are implemented in relation to cleaning, disinfection, inspection, packaging, sterilisation, transportation and storage of such devices.

(4) The procedures implemented in accordance with paragraph (3) must be such as to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.

(5) The registered person must protect patients against the risks associated with the unsafe use and management of medicines, by means of—

- (a) the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used in or for the purposes of the establishment or agency; and
- (b) having regard to any guidance issued by the registration authority or appropriate expert body in relation to the safe handling and use of medicines.

(6) The registered person must ensure that where blood and blood products are used a monitoring process for the safety of blood transfusion (haemovigilance) is in place.

(7) The registered person must, so far as reasonably practicable, ensure that—

- (a) patients; and
- (b) others who may be at risk of exposure to a health care associated infection arising from working in or for the purposes of an establishment or agency,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (8).

- (8) The means referred to in paragraph (7) are—
- (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care associated infection;
  - (b) where applicable, the provision of appropriate treatment for those who are affected by a health care associated infection; and
  - (c) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
    - (i) premises occupied for the purpose of carrying on the establishment or agency;
    - (ii) equipment and reusable medical devices used for the purpose of carrying on the establishment or agency; and
    - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated with a health care associated infection.

(9) If an establishment provides food and drink for patients as a component of the patients' care, the registered person must ensure that—

- (a) Patients' nutritional and hydration needs are assessed and documented on admission and at regular intervals thereafter;
- (b) Food and hydration is provided that meets individual patient nutritional and hydration needs.

(10) The registered person must take account of any advice bulletins relating to the type of treatment the establishment or agency provides and to patient safety information published by appropriate regulatory, professional or appropriate statutory expert bodies.

### **Safeguarding patients from abuse**

**16.—**(1) The registered person must make suitable arrangements to ensure that patients are safeguarded against the risk of abuse by means of—

- (a) taking reasonable steps to identify the possibility of abuse and prevent it before it occurs; and
- (b) responding appropriately to any allegation of abuse.

(2) Where any form of control or restraint is used in the establishment or for the purposes of an agency, the registered person must have suitable arrangements in place to protect patients against the risk of such control or restraint being—

- (a) unlawful; or
- (b) otherwise excessive.

(3) The registered person must have regard to any guidance issued by the registration authority or appropriate expert body, in relation to—

- (a) the protection of children and vulnerable adults generally; and
- (b) in particular, the appropriate use of methods of control or restraint.

(4) For the purposes of paragraph (1), “abuse” (“*cam-drin*”), in relation to a patient, means—

- (a) sexual abuse;
- (b) physical or psychological ill-treatment;
- (c) theft, misuse or misappropriation of money or property; or
- (d) neglect and acts of omission which cause harm or place at risk of harm.

### **Capacity of patients**

17.—(1) The registered person must, so far as is practicable, and, where the patient lacks capacity, in accordance with the principles of the 2005 Act enable each patient to make decisions about matters affecting the way in which the patient is cared for and his or her welfare.

(2) The registered person must ensure that patients are enabled to control their own money, except where a patient does not wish, or lacks capacity to do so, in which case the registered person must ensure that patient monies are properly held and recorded and that receipts are issued as appropriate.

(3) The registered person must so far as practicable, and where patients lack capacity, in accordance with the principles of the 2005 Act ascertain and take into account the wishes and feelings of all patients in determining the manner in which they are cared for and services are provided to them.

### **Privacy, dignity and relationships**

18.—(1) The registered person must make suitable arrangements to ensure that the establishment or agency is conducted—

- (a) in a manner which respects the privacy and dignity of patients; and
- (b) with due regard to the sex, religious persuasion, racial origin, sexual orientation, cultural and linguistic background and any disability of patients.

(2) The registered provider and the registered manager (if any) must each take all reasonable steps to ensure that the establishment or agency is conducted on the basis of good personal and professional relationships—

- (a) between each other; and
- (b) between each of them and the patients and staff.

### **Assessing and monitoring the quality of service provision including annual returns**

19.—(1) The registered person must protect patients, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the establishment or agency against the requirements set out in these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of patients and others.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
  - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by patients, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 24;
  - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the establishment or agency;
  - (iii) the information contained in the records referred to in regulation 23;
  - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a));
  - (v) reports prepared by the registration authority from time to time pursuant to section 32(5) of the Act in relation to the establishment or agency;

- (c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—
  - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a patient; and
  - (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;
- (d) establish mechanisms for ensuring that decisions in relation to the provision of care and treatment for patients are taken at the appropriate level and by an appropriate person; and
- (e) regularly seek the views (including the descriptions of their experiences of care and treatment) of patients, persons acting on their behalf, persons who are employed for the purposes of the establishment or agency and any medical practitioner with practising privileges, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to patients.

(3) The registered person must send to the appropriate office of the registration authority, when requested to do so, a written annual assessment (referred to as the “annual return”) setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with in relation to the establishment or agency, together with any plans that the registered person has for improving the standard of the services provided to patients with a view to ensuring their health and welfare.

(4) The registered person must take reasonable steps to ensure that the annual return is not misleading or inaccurate.

(5) The registered person must supply the annual return to the appropriate office of the registration authority within 28 days of receiving a request under paragraph (3).

### **Staffing**

**20.—**(1) The registered person must, having regard to the nature of the establishment or agency, the statement of purpose and the number and needs of patients—

- (a) ensure that at all times suitably qualified, skilled and experienced persons are working in or for the purposes of the establishment or as the case may be, for the purposes of the agency, in such numbers as are appropriate for the health and welfare of the patients;
- (b) ensure that the employment of any persons on a temporary basis in or for the purposes of the establishment or for the purposes of the agency will not prevent patients from receiving such continuity of care as is reasonable to meet their needs.

(2) The registered person must ensure that each person employed in or for the purposes of the establishment, or for the purposes of the agency—

- (a) receives appropriate training, supervision and appraisal;
- (b) is enabled from time to time to obtain further qualifications appropriate to the work the person performs; and
- (c) is provided with a job description outlining the person’s responsibilities.

(3) The registered person must ensure that each person employed in or for the purposes of the establishment or for the purposes of the agency and any medical practitioner with practising privileges, receives regular and appropriate appraisal and must take such steps as may be necessary to address any aspect of—

- (a) a health care professional’s clinical practice; or
- (b) the performance of a member of staff who is not a health care professional,

which is found to be unsatisfactory.

(4) The registered person must take reasonable steps to ensure that any persons working in or for the purposes of an establishment or for the purposes of an agency who are not employed by the registered person and to whom paragraph (2) does not apply, are appropriately supervised to ensure patients' health and welfare is not compromised, while carrying out their duties.

### **Fitness of workers**

**21.—**(1) Subject to paragraph (4) the registered person must not—

- (a) employ under a contract of employment a person to work in or for the purposes of the establishment or for the purposes of the agency unless that person is fit to do so;
- (b) allow a volunteer to work in or for the purposes of the establishment or for the purposes of the agency unless that person is fit to do so;
- (c) allow any other person (including a medical practitioner seeking the grant of practising privileges) to work in or for the establishment or for the purposes of the agency in a position in which he or she may in the course of his or her duties have regular contact with a patient unless that person is fit to work in or for the establishment or for the purposes of the agency.

(2) For the purposes of paragraph (1) a person is not fit to work in or for the purposes of an establishment or for the purposes of an agency unless—

- (a) the person is of suitable integrity and good character for the work which the person is to perform;
- (b) the person has the qualifications, skills and experience which are necessary for that work;
- (c) the person is physically and mentally fit for that work; and
- (d) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.

(3) The certificate referred to in paragraph 3 of Schedule 2 must be applied for by, or on behalf of the registered person, for the purpose of assessing the suitability of a person for the post referred to in paragraph (1).

(4) The registered person must ensure that—

- (a) any offer of employment to, or other arrangement about working in or for the purposes of the establishment or for the purposes of the agency made with or in respect of a person described in paragraph (1) is subject to paragraph (2)(d) being complied with in relation to that person; and
- (b) unless paragraph (5) applies, no such person starts work in or for the purposes of the establishment or for the purposes of the agency until such time as paragraph (2)(d) has been complied with in relation to that person.

(5) Where the following conditions apply, the registered person may permit a person other than a health care professional to start work in or for the purposes of the establishment or for the purposes of an agency notwithstanding paragraphs (1) and (4)(b)—

- (a) the registered person has taken all reasonable steps to obtain full information in respect of each of the matters listed in paragraphs 1 and 3 to 8 of Schedule 2 in respect of that person, but the enquiries in relation to any of the matters listed in paragraphs 4 to 8 of Schedule 2 are incomplete;
- (b) full and satisfactory information in relation to that person has been obtained in respect of the matters specified in paragraphs 1 and 3 of Schedule 2;
- (c) in the reasonable opinion of the registered person the circumstances are exceptional; and

(d) pending receipt of, and being satisfied with regard to, any outstanding information, the registered person ensures that the person is appropriately supervised while carrying out his or her duties.

(6) The registered person must ensure that any person working in or for the purposes of the establishment or agency who does not fall within paragraph (1) is appropriately supervised at all times when they are in contact with patients.

### **Guidance for health care professionals**

**22.** The registered person must ensure that any code of ethics or professional practice prepared by a body which is responsible for regulation of members of a health care profession is made available in the establishment or agency to members of the health care profession in question.

### **Records**

**23.—**(1) The registered person must ensure that except in cases to which regulation 43(5) applies—

- (a) a comprehensive health care record which may be in paper or electronic form is maintained in relation to each patient, which includes—
  - (i) a contemporaneous note of all treatment provided to the patient;
  - (ii) the patient’s medical history and all other notes prepared by a health care professional about the patient’s case; and
- (b) the record is retained for a period which is not less than that specified in Part I of Schedule 3 in relation to the type of patient in question or, where more than one such period could apply, the longest of them.

(2) The registered person must ensure that—

- (a) the health care record for a person who is currently a patient is kept in a secure place in the establishment or agency premises; and
- (b) the health care record for a person who is not currently a patient is stored securely (whether in the establishment or agency or elsewhere) and that it can be located if required.

(3) In addition to the health care records maintained in accordance with paragraph (1), the registered person must ensure that the records, which may be in paper or electronic form, specified in Part II of Schedule 3 are maintained and that they are—

- (a) kept up to date;
- (b) at all times available for inspection in the establishment or agency by any person authorised by the registration authority to enter and inspect the establishment or agency; and
- (c) retained for a period of not less than three years beginning on the date of the last entry.

(4) Where an establishment or agency closes the registered person must ensure that the records maintained in accordance with paragraphs (1) and (3) are kept securely elsewhere and must make them available for inspection by the registration authority at its request.

### **Complaints**

**24.—**(1) The registered person must establish a procedure (in these Regulations referred to as “the complaints procedure”) for considering complaints made to the registered person by a patient or a person acting on behalf of a patient.

(2) The registered person must ensure that any complaint made under the complaints procedure is fully investigated.

- (3) The registered person must supply a written copy of the complaints procedure upon request, to—
- (a) every patient;
  - (b) any person acting on behalf of a patient; and
  - (c) any person who is considering whether to become a patient.
- (4) The written copy of the complaints procedure must include—
- (a) the name, address and telephone number of the appropriate office of the registration authority; and
  - (b) the procedure (if any) which has been notified by the registration authority to the registered person for making complaints to the registration authority relating to the establishment or agency.
- (5) The registered person must maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence including whether any action is necessary to improve the quality of treatment or services and the requirements of regulation 23(3) (b) and (c) will apply to that record.
- (6) The registered person must supply to the registration authority at its request copies of records maintained under paragraph (5).

## **Research**

- 25.**—(1) The registered person must ensure that—
- (a) before any research involving patients, information about patients, or human tissue is undertaken in or for the purposes of an establishment, a research proposal is prepared and approval is obtained from the appropriate Research Ethics Committee; and
  - (b) all such research projects include adequate safeguards for patients and employees.
- (2) For the purposes of paragraph (1)(a), “the appropriate Research Ethics Committee” (“*y Pwyllgor Moeseg Ymchwil priodol*”) means a research ethics committee established in accordance with guidance issued from time to time by the registration authority or appropriate expert body.