
WELSH STATUTORY INSTRUMENTS

2002 No. 325

Private and Voluntary Health Care (Wales) Regulations 2002

PART III

CONDUCT OF HEALTH CARE ESTABLISHMENTS

CHAPTER 1

QUALITY OF SERVICE PROVISION

Quality of treatment and other service provision

14.—(1) Subject to regulation 5(4), the registered person shall provide treatment and any other services to patients in accordance with the statement of purpose, and shall ensure that the treatment and any other services provided to each patient—

- (a) meet the patient's individual needs; and
- (b) reflect published research evidence, and guidance issued by the appropriate professional and expert bodies, as to good practice in the treatment of the condition from which the patient is suffering; and
- (c) are (where necessary) provided by means of appropriate equipment.

(2) The registered person shall ensure that all equipment used in or for the purposes of the establishment is—

- (a) suitable for the purposes for which it is to be used; and
- (b) properly maintained and in good working order.

(3) Where reusable medical devices are used in an establishment, the registered person shall 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) shall be such as to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.

(5) The registered person shall make suitable arrangements for the ordering, recording, handling, safe keeping, safe administration and disposal of drugs used in or for the purposes of the establishment.

(6) The registered person shall make suitable arrangements to minimise the risk of infection and toxic conditions and the spread of infection between patients and staff (including medical practitioners with practising privileges).

(7) If an establishment provides food for patients, the registered provider shall ensure that it is—

- (a) provided in adequate quantities and at appropriate intervals;
- (b) properly prepared, wholesome and nutritious; and
- (c) suitable for the needs of patients;

and that the menu is varied at suitable intervals.

Care and welfare of patients

15.—(1) The registered person shall ensure that the establishment is conducted so as to promote and make proper provision for the welfare of patients and shall, so far as practicable, enable patients to make decisions about matters affecting their care and general welfare.

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

(3) The registered person shall, so far as practicable, 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.

(4) The registered person shall make suitable arrangements to ensure that the establishment 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, and cultural and linguistic background and any disability of patients.

(5) The registered provider and the registered manager (if any) shall each take all reasonable steps to ensure that the establishment 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.

Review of quality of treatment and other services

16.—(1) The registered person shall introduce and maintain a system for reviewing at appropriate intervals the quality of treatment and other services provided in or for the purposes of an establishment.

(2) The registered person shall supply to the appropriate office of the National Assembly a report in respect of any review conducted by the registered person for the purposes of paragraph (1) and make a copy of the report available to patients.

(3) The system referred to in paragraph (1) shall provide for consultation with patients and their representatives.

Staffing

17.—(1) The registered person shall, having regard to the nature of the establishment, 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 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 will not prevent patients from receiving such continuity of care as is reasonable to meet their needs.

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

- (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 shall ensure that each person employed in or for the purposes of the establishment and any medical practitioner with practising privileges, receives regular and appropriate appraisal and shall 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 shall take reasonable steps to ensure that any persons working in or for the purposes of an establishment who are not employed by the registered person and to whom paragraph (2) does not apply, are appropriately supervised while carrying out their duties.

Fitness of workers

18.—(1) The registered person shall not—

(a) employ under a contract of employment a person to work in or for the purposes of the establishment unless that person is fit to do so ;

(b) allow a volunteer to work in or for the purposes of the establishment 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 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.

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

(i) except where paragraph (3) applies, in respect of each of the matters specified in paragraphs 1 to 7 of Schedule 2;

(ii) where paragraph (3) applies, in respect of each of the matters specified in paragraphs 1 and 3 to 8 of Schedule 2.

(3) This paragraph applies where any certificate or information on any matters referred to in paragraph 2 of Schedule 2 is not available because any provision of the Police Act 1997(1) has not been brought into force.

(4) The registered person shall ensure that—

(a) any offer of employment to, or other arrangement about working in or for the purposes of the establishment 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 until such time as paragraph (2)(d) has been complied with in relation to that person.

(1) See footnote to regulation 9(4).

(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 notwithstanding paragraph (4)(b)—

- (a) the registered person has taken all reasonable steps to obtain full information in respect of each of the matters listed in Schedule 2 in respect of that person, but the enquiries in relation to any of the matters listed in paragraphs 3 to 6 of Schedule 2 are incomplete;
- (b) full and satisfactory information in relation to that person has been obtained in respect of—
 - (i) the matter specified in paragraph 1 of Schedule 2; and
 - (ii) unless paragraph (3) applies, the matter specified in paragraph 2 of that Schedule; or
 - (iii) where paragraph (3) applies, the matter specified in paragraph 8 of that Schedule;
- (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 shall ensure that any person working in or for the purposes of the establishment 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

19. The registered person shall 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 to members of the health care profession in question.

Records

20.—(1) The registered person shall ensure that except in cases to which regulation 39(5) applies—

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

(3) In addition to the medical records maintained in accordance with paragraph (1), the registered person shall ensure that the records 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 by any person authorised by the National Assembly to enter and inspect the establishment ; and
- (c) retained for a period of not less than three years beginning on the date of the last entry.

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

Staff views as to conduct of establishment

21.—(1) This regulation applies to any matter relating to the conduct of the establishment so far as it may affect the health or welfare of patients.

(2) The registered person shall make arrangements to enable any person employed in or for the purposes of the establishment and any medical practitioner with practising privileges to inform the registered person and the National Assembly of their views about any matter to which this regulation applies.

Complaints

22.—(1) The registered person shall 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 shall ensure that any complaint made under the complaints procedure is fully investigated.

(3) The registered person shall 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 shall include—

- (a) the name, address and telephone number of the appropriate office of the National Assembly; and
- (b) the procedure (if any) which has been notified by the National Assembly to the registered person for making complaints to the National Assembly relating to the establishment.

(5) The registered person shall maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence and the requirements of regulation 20(3)(b) and (c) shall apply to that record.

(6) The registered person shall supply to the National Assembly at its request copies of records maintained under paragraph (5).

Research

23.—(1) The registered person shall 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” means a research ethics committee established in accordance with guidance issued from time to time by the National Assembly.

CHAPTER 2

PREMISES

Fitness of premises

24.—(1) The registered person shall not use premises as an establishment unless they are in a location, and of a physical design and layout, which are suitable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person shall ensure that—

- (a) the premises are of sound construction and kept in a good state of repair externally and internally;
- (b) the size and layout of rooms are suitable for the purposes for which they are to be used and are suitably equipped and furnished;
- (c) all parts of the establishment are kept clean and meet appropriate standards of hygiene;
- (d) all parts of the establishment to which patients have access are so far as reasonably practicable free from hazards to their safety; and
- (e) if surgical procedures are undertaken, life support systems are used, or obstetric services and, in connection with childbirth, medical services, are provided in the establishment, such electrical supply is provided during the interruption of public supply as is needed to safeguard the lives of the patients.

(3) The registered person shall provide for employees and medical practitioners with practising privileges—

- (a) suitable facilities and accommodation, other than sleeping accommodation, including—
 - (i) facilities for the purpose of changing; and
 - (ii) storage facilities; and
- (b) where the provision of such accommodation is needed by employees in connection with their work, sleeping accommodation.

(4) The registered person shall—

- (a) take adequate precautions against the risk of fire, including the provision and maintenance of adequate fire prevention and detection equipment;
- (b) provide adequate means of escape in the event of a fire;
- (c) make arrangements for persons employed in the establishment and medical practitioners to whom practising privileges have been granted to receive suitable training in fire prevention;
- (d) ensure, by means of fire drills and practices at suitable intervals, that the persons employed in the establishment and, so far as practicable, patients and medical practitioners to whom practising privileges have been granted, are aware of the procedure to be followed in case of fire;
- (e) review fire precautions, the suitability of fire equipment and the procedure to be followed in case of fire at intervals not exceeding twelve months; and
- (f) consult with the fire authority about the matters described in sub-paragraphs (a) to (e).

(5) In this regulation, “fire authority”, in relation to an establishment, means the authority discharging in the area in which the establishment is situated, the function of fire authority under the Fire Services Act 1947(2).

CHAPTER 3 MANAGEMENT

Visits by registered provider

25.—(1) Where the registered provider is an individual who does not manage the establishment, that individual shall visit the establishment in accordance with this regulation.

(2) Where the registered provider is an organisation, the establishment shall be visited in accordance with this regulation by—

- (a) the responsible individual;
- (b) another of the directors or other persons responsible for the management of the organisation who is suitable to visit the establishment; or
- (c) an employee of the organisation who has appropriate qualifications, skills and experience for the purpose and who is not directly concerned with the conduct of the establishment.

(3) Visits under paragraph (1) or (2) shall take place at least every three months and may be unannounced.

(4) The person carrying out the visit shall—

- (a) interview, with their consent and in private (if necessary, by telephone), such of the patients and their representatives and such employees as appear to be necessary in order to form an opinion of the standard of treatment and other services provided in or for the purposes of the establishment;
- (b) inspect the premises and records of any complaints; and
- (c) prepare a written report on the conduct of the establishment.

(5) The registered provider shall supply a copy of the report required to be made under paragraph (4)(c) to—

- (a) the National Assembly;
- (b) the registered manager; and
- (c) in the case of a visit under paragraph (2), to each of the directors or other persons responsible for the management of the organisation.

Financial position

26.—(1) The registered provider shall carry on the establishment in such manner as is likely to ensure that the establishment will be financially viable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person shall, if the National Assembly so requests, provide it with such information and documents as it may require for the purpose of considering the financial viability of the establishment, including—

- (a) the annual accounts of the establishment, certified by an accountant; or
- (b) the annual accounts of the organisation which is the registered provider of the establishment, certified by an accountant, together with accounts relating to the establishment itself.

(3) The registered person shall also provide the National Assembly with such other information as it may require in order to consider the financial viability of the establishment, including—

- (a) a reference from a bank expressing an opinion as to the registered provider's financial standing;

- (b) information as to the financing and financial resources of the establishment ;
 - (c) where the registered provider is a company, information as to any of its associated companies; and
 - (d) a certificate of insurance for the registered provider in respect of liability which may be incurred by the provider in relation to the establishment in respect of death, injury, public liability, damage or other loss.
- (4) In this regulation, one company is associated with another if one of them has control of the other, or both are under the control of the same person.

CHAPTER 4

NOTICES TO BE GIVEN TO THE NATIONAL ASSEMBLY

Notification of events

27.—(1) The registered person shall give notice to the appropriate office of the National Assembly of—

- (a) the death of a patient—
 - (i) in an establishment;
 - (ii) during treatment provided in or for the purposes of an establishment; or
 - (iii) as a consequence of treatment provided in or for the purposes of an establishment, within the period of seven days ending on the date of death;and the circumstances of the patient's death;
- (b) any serious injury to a patient;
- (c) the outbreak in an establishment of any infectious disease, which in the opinion of any medical practitioner employed in the establishment is sufficiently serious to be so notified;
- (d) any allegation of misconduct resulting in actual or potential harm to a patient by the registered person, any person employed in or for the purposes of the establishment, or any medical practitioner with practising privileges.

(2) Notice under paragraph (1) shall be given within the period of 24 hours beginning with the event in question and, if given orally, shall be confirmed in writing as soon as practicable.

Notice of absence

28.—(1) Where—

- (a) a registered provider in respect of whom a notification has been given under regulation 10(3); or
- (b) a registered manager,

proposes to be absent from the establishment for a continuous period of 28 days or more, the registered person shall give notice in writing to the appropriate office of the National Assembly of the absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) shall be given no later than one month before the proposed absence commences or within such shorter period as may be agreed with the National Assembly and the notice shall specify with respect to the absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for running the establishment;

- (d) the name, address and qualifications of the person who will be responsible for the establishment during that absence; and
- (e) the arrangements that have been or are proposed to be made for appointing another person to manage the establishment during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence arises as a result of an emergency, the registered person shall give notice of the absence within one week of the emergency's occurrence specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(4) Where—

- (a) a registered provider in respect of whom a notification has been given under regulation 10(3); or
- (b) a registered manager,

has been absent from the establishment for a continuous period of 28 days or more, and the appropriate office of the National Assembly has not been given notice of the absence, the registered person shall, without delay, give notice in writing to that office, specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(5) The registered person shall notify the appropriate office of the National Assembly of the return to work of a person mentioned in sub-paragraph (a) or (b) of paragraph (4) not later than 7 days after the date of that person's return.

Notice of changes

29. The registered person shall give notice in writing to the appropriate office of the National Assembly as soon as it is practicable to do so if any of the following events take place or are proposed to take place—

- (a) a person other than the registered person carries on or manages the establishment;
- (b) a person ceases to carry on or manage the establishment;
- (c) where the registered person is an individual, he or she changes his or her name;
- (d) where the registered is an individual, that individual changes his or her name;
- (e) where the registered provider is an organisation—
 - (i) the name or address of the organisation is changed;
 - (ii) there is any change of director, manager, secretary or other similar officer of the organisation;
- (f) there is any change in the identity of the responsible individual;
- (g) Where the registered provider is an individual, a trustee in bankruptcy is appointed or a composition or arrangement is made with creditors;
- (h) where the registered provider is a company or partnership, a receiver, manager, liquidator or provisional liquidator is appointed; or
- (i) the premises of the establishment are significantly altered or extended, or additional premises are acquired.

Appointment of liquidators etc.

30.—(1) Any person to whom paragraph (2) applies shall—

- (a) forthwith notify the appropriate office of the National Assembly of the person's appointment indicating the reasons for it;

- (b) appoint a manager to take full-time day to day charge of the establishment in any case where the duty under regulation 10(1) is not being met; and
 - (c) before the end of the period of 28 days beginning on the date of the person's appointment, notify the appropriate office of the National Assembly of the person's intentions regarding the future operation of the establishment to which the appointment relates.
- (2) This paragraph applies to any person appointed as—
- (a) the receiver or manager of the property of a company or partnership which is a registered provider of an establishment;
 - (b) a liquidator or provisional liquidator of a company which is the registered provider of an establishment;
 - (c) the receiver or manager of the property of a partnership whose business includes carrying on an establishment;
 - (d) the trustee in bankruptcy of a registered provider of an establishment.

Death of registered person

31.—(1) If more than one person is registered in respect of an establishment, and a registered person dies, the surviving registered person shall without delay notify the appropriate office of the National Assembly of the death in writing.

(2) If only one person is registered in respect of an establishment, and the person dies, the person's personal representatives shall notify the appropriate office of the National Assembly in writing—

- (a) without delay of the death; and
- (b) within 28 days of their intentions regarding the future running of the establishment.

(3) The personal representatives of the deceased registered provider may carry on the establishment without being registered in respect of it

- (a) for a period not exceeding 28 days; and
- (b) for any further period as may be determined by the National Assembly in accordance with paragraph (4).

(4) The National Assembly may extend the period specified in paragraph (3)(a) by such further period, not exceeding one year, as the National Assembly shall determine, and shall notify any such determination to the personal representatives in writing.

(5) The personal representatives shall appoint a person to take full-time day to day charge of the establishment during any period in which, in accordance with paragraph (3), they carry on the establishment without being registered in respect of it.