
STATUTORY RULES OF NORTHERN IRELAND

2005 No. 174

**The Independent Health Care
Regulations (Northern Ireland) 2005**

PART III

CONDUCT OF HEALTH CARE ESTABLISHMENTS AND AGENCIES

QUALITY OF SERVICE PROVISION

Quality of treatment and other service provision

15.—(1) Subject to regulation 7(3), 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 his individual needs;
- (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, or for the purposes of the agency is –

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

(3) Where reusable medical devices are used in an establishment or agency, 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 registered person shall ensure that medical devices designated for single use only are not re-used under any circumstances.

(5) 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.

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

(7) 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).

(8) The registered person shall ensure that patients receive a comprehensive outpatient service.

(9) 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

16.—(1) The registered person shall, so far as practicable, enable each patient to make decisions about matters affecting the way in which he is cared for and his 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 the 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 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 and spiritual needs, ethnic 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 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.

(6) The registered person shall ensure that the patient’s general practitioner is kept informed of relevant developments including significant family distress and this action is documented.

(7) The registered person shall ensure that the information and communication procedures for the establishment or agency meet the needs of patients, their families and staff

Review of quality of treatment and other services

17.—(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 or for the purposes of an agency.

(2) The registered person shall supply to the Regulation and Improvement Authority a report in respect of any review conducted by him 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.

(4) Where shortcomings in systems are highlighted as a result of an investigation, additional safeguards are put in place.

(5) The registered person shall ensure there are arrangements for identifying, recording, analysing and learning from adverse incidents.

Staffing

18.—(1) The registered person shall, having regard to the nature of the establishment or agency, the statement of purpose and the number and needs of patients, ensure that there is at all times an appropriate number of suitably qualified, skilled and experienced persons employed in or for the purposes of the establishment or, as the case may be, for the purposes of the agency.

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

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

(3) The registered person shall 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 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 person working in an establishment or agency who is not employed by him and to whom paragraph (2) does not apply, is appropriately supervised while carrying out his duties.

(5) The registered person shall maintain a record of the rostered shifts for each employee and a record of the hours worked by each person.

Fitness of workers

19.—(1) The registered person shall ensure that –

- (a) no person is employed to work in or for the purpose of the establishment or for the purpose of the agency;
- (b) no medical practitioner is granted consulting or practising privileges, unless that person is fit to work in or for the purpose of the establishment, or for the purposes of the agency; and
- (c) there is evidence that all professional registration and revaluation requirements are met.

(2) A person is not fit to work in or for the purposes of an establishment, or for the purposes of an agency unless –

- (a) he is of integrity and good character.
- (b) he has the qualifications, skills and experience which are necessary for the work which he is to perform;
- (c) he is physically and mentally fit for that work; and
- (d) full and satisfactory information is available in relation to him in respect of each of the matters specified in Schedule 2.

(3) The registered person shall ensure that all healthcare professionals are covered by appropriate professional indemnity.

Guidance for health care professionals.

20. 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 or agency to members of the health care profession in question.

Records

- 21.—(1) The registered person shall ensure that –
- (a) a comprehensive medical record is maintained in relation to each patient, which includes –
 - (i) a contemporaneous note of all treatment provided to him;
 - (ii) his medical history and all other notes prepared by a health care professional about his 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 or the agency premises; and
 - (b) the medical record for a person who is not currently a patient is stored securely (whether in the establishment or the agency premises or elsewhere) and that it can be located if required.
- (3) 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 or the agency premises by any person authorised by the Regulation and Improvement Authority to enter and inspect the establishment or agency premises; and
 - (c) retained for a period of time not less than three years beginning on the date of the last entry.

Staff views as to conduct of establishment or agency

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

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

Complaints

23.—(1) The registered person shall establish a procedure (in these Regulations referred to as “the complaints procedure”) for receiving, managing and responding to complaints made to the registered person by a patient or a person acting on behalf of a patient.

(2) The complaints procedure shall be appropriate to the needs of patients.

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

(4) The registered person shall, within 28 days after the date on which the complaint is made, or such shorter period as may be reasonable in the circumstances, inform the person who made the complaint of the investigative process, outcome and action (if any) that is to be taken.

(5) The registered person shall supply a written copy of the complaints procedure to every patient and, upon request, to –

- (a) any person acting on behalf of a patient; and
- (b) any person who is considering whether to become a patient.

(6) The copy of the complaints procedure shall include –

- (a) the name, address and telephone number of the Regulation and Improvement Authority; and
- (b) the procedure (if any) which has been notified by the Regulation and Improvement Authority to the registered person for making complaints to the Regulation and Improvement Authority relating to the establishment or agency.

(7) 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 21(3)(b) and (c) shall apply to that record.

(8) The registered person shall supply to the Regulation and Improvement Authority annually a statement containing a summary of the complaints made during the preceding twelve months and the action taken in response.

Clinical trials and research

24. The registered person shall ensure that –

- (a) before any research involving patients, information about patients is undertaken in or for the purposes of the establishment or agency, a research proposal is prepared and approval is obtained from the appropriate Ethics Committee;
- (b) any clinical trial to be conducted in the establishment or agency has been authorised in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004(1).

PREMISES

Fitness of premises

25.—(1) Subject to regulation 7(3), the premises used as an establishment or agency must be 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 or agency are kept clean and meet appropriate standards of hygiene;
- (d) all parts of the establishment or agency 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, and 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, after consultation with the Fire Authority –
 - (a) take adequate precautions against the risk of fire, including the provision and maintenance of suitable fire equipment;
 - (b) provide adequate means of escape in the event of fire;
 - (c) make arrangements for persons employed in the establishment or for the purposes of the agency 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 or for the purposes of the agency 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; and
 - (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;
 - (f) carry out a fire risk assessment of the premises and identify the significant findings of the risk assessment and the details of anyone who might be especially at risk.

MANAGEMENT

Visits by registered provider

26.—(1) Where the registered provider is an individual but is not in day-to-day charge of the establishment or agency, he shall visit the establishment or agency premises in accordance with this regulation.

(2) Where the registered provider is an organisation or a partnership, the establishment or agency shall be visited in accordance with this regulation by –

- (a) the responsible individual or one of the partners, as the case may be;
- (b) another of the directors or other persons responsible for the management of the organisation or partnership; or
- (c) an employee of the organisation or partnership who is not directly concerned with the conduct of the establishment or agency.

(3) Visits under paragraph (1) or (2) shall take place at least once every six months and shall 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 appears to him 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, or for the purposes of the agency;
 - (b) inspect records of any complaints and, in the case of an establishment, its premises; and
 - (c) prepare a written report on the conduct of the establishment or agency.
- (5) The registered provider shall maintain a copy of the report required to be made under paragraph (4)(c) on the establishment or agency and make it available on request to –
- (a) the Regulation and Improvement Authority;
 - (b) the registered manager;
 - (c) the patient or their representative.
- (6) In the case of a visit under paragraph (2) –
- (i) where the registered provider is an organisation, to each of the directors or other persons responsible for the management of the organisation; and
 - (ii) where the registered provider is a partnership, to each of the partners.

Financial position

27.—(1) The registered provider shall carry on the establishment or agency in such manner as is likely to ensure that the establishment or agency 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 Regulation and Improvement Authority so requests, provide the Regulation and Improvement Authority with such information and documents as it may require for the purpose of considering the financial viability of the establishment or agency, including –

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

(3) The registered person shall also provide the Regulation and Improvement Authority with such other information as it may require in order to consider the financial viability of the establishment or agency, 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 or agency;
- (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 him in relation to the establishment or agency 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.

NOTICES TO BE GIVEN TO THE REGULATION AND IMPROVEMENT AUTHORITY

Notification of deaths and other events

28.—(1) The registered person shall give notice to the Regulation and Improvement Authority of –

- (a) the death of a patient –
 - (i) in an establishment;
 - (ii) during treatment provided by an establishment or agency; or
 - (iii) as a consequence of treatment provided by an establishment or agency within the period of seven days ending on the date of the death, and the circumstances of his 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 event in the establishment or agency which adversely affects the well-being or safety of any patient;
- (e) 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 for the purposes of the agency, or any medical practitioner with practising privileges;
- (f) any theft, burglary or accident in the establishment or agency.

(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

29.—(1) Where –

- (a) the registered provider, if he is the person in day-to-day charge of the establishment or agency; or
- (b) the registered manager,

proposes to be absent from the establishment or agency for a continuous period of 28 days or more, the registered person shall give notice in writing to the Regulation and Improvement Authority of the proposed 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 Regulation and Improvement Authority and the notice shall specify with respect to the proposed absence –

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for running the establishment or agency;
- (d) the name, address and qualifications of the person who will be responsible for the establishment or agency during that absence; and
- (e) in the case of the absence of the registered manager, the arrangements that have been, or are proposed to be, made for appointing another person to manage the establishment or agency during that absence, including the proposed date by which the appoint 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 its occurrence specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(4) Where –

- (a) the registered provider, if he is the person in day-to-day charge of the establishment or agency; or
- (b) the registered manager;

has been absent from the establishment or agency for a continuous period of 28 days or more, and the Regulation and Improvement Authority has not been given notice of the absence, the registered person, shall, without delay, give notice in writing to the Regulation and Improvement Authority of the absence, specifying the matters set out in paragraph (2)(a) to (e).

(5) The registered person shall notify the Regulation and Improvement Authority of the return to duty of the registered provider or (as the case may be) the registered manager not later than 7 days after the date of his return.

Notice of changes

30. The registered person shall give notice in writing to the Regulation and Improvement Authority 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 or agency;
- (b) a person ceases to carry on or manage the establishment or agency;
- (c) where the registered provider is an individual, he changes his name;
- (d) where the registered provider is a partnership, there is any change in the membership of the partnership;
- (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;
 - (iii) there is any change in the identity of the responsible individual;
- (f) where the registered provider is an individual, a trustee in bankruptcy is appointed;
- (g) where the registered provider is a company or partnership, a receiver, manager, liquidator or provisional liquidator is appointed; or
- (h) the premises of the establishment or agency are significantly altered or extended, or additional premises are acquired.

Appointment of liquidators etc

31.—(1) Any person to whom paragraph (2) applies must –

- (a) forthwith notify the Regulation and Improvement Authority of his appointment indicating the reasons for it;
- (b) appoint a manager to take full-time day-to-day charge of the establishment or agency in any case where there is no registered manager; and
- (c) before the end of the period of 28 days beginning on the date of his appointment, notify the Regulation and Improvement Authority of his intentions regarding the future operation of the establishment or agency.

(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 or agency;
- (b) liquidator or provisional liquidator of a company which is the registered provider of an establishment or agency;
- (c) the trustee in bankruptcy of a registered provider of an establishment or agency.

Death of registered person

32.—(1) If more than one person is registered in respect of an establishment or agency, and a registered person dies, the surviving registered person shall without delay notify the Regulation and Improvement Authority of the death in writing.

(2) If only one person is registered in respect of an establishment or agency, and he dies, his personal representatives must notify the Regulation and Improvement Authority in writing –

(a) without delay of the death; and

(b) within 28 days of their intentions regarding the future running of the establishment or agency.

(3) The personal representatives of the deceased registered provider may carry on the establishment or agency 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 in accordance with paragraph (4).

(4) The Regulation and Improvement Authority may extend the period specified in paragraph (3) (a) by such further period, not exceeding one year, as the Regulation and Improvement Authority 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 or agency during any period in which, in accordance with paragraph (3), they carry on the establishment or agency without being registered in respect of it.