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**).

(**1**) S.I.2004/1031