

2005 No. 174

HEALTH AND PERSONAL SOCIAL SERVICES

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

Made - - - - - *25th March 2005*

Coming into operation *1st April 2005*

ARRANGEMENT OF REGULATIONS

**PART I
GENERAL**

1. Citation, commencement and extent
2. Interpretation
3. Exceptions to the definition of independent hospital
4. Prescribed techniques or technology
5. Meaning of independent clinic
6. Exception of undertaking from the definition of independent medical agency
7. Statement of purpose
8. Patient's guide
9. Review of statement of purpose and patient's guide

**PART II
REGISTERED PERSONS**

10. Fitness of registered provider
11. Appointment of manager
12. Fitness of registered manager
14. Registered person: general requirements
14. Registered person: notification of offences

**PART III
CONDUCT OF HEALTH CARE ESTABLISHMENTS AND AGENCIES**

Quality of service provision

15. Quality of treatment and other service provision
16. Care and welfare of patients
17. Review of quality of treatment and other services
18. Staffing

19. Fitness of workers
20. Guidance for health care professionals
21. Records
22. Staff views as to conduct of establishment or agency
23. Complaints
24. Clinical trials and research

Premises

25. Fitness of premises

Management

26. Visits by registered provider
27. Financial position

Notices to be given to the Regulation and Improvement Authority

28. Notification of death and other events
29. Notice of absence
30. Notice of changes
31. Appointment of liquidators etc.
32. Death of registered person

PART IV

ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT HOSPITALS

Pathology services, resuscitation and treatment of children in independent hospitals

33. Application of regulations 34 to 36
34. Pathology services
35. Resuscitation
36. Treatment of children

Independent hospitals in which certain listed services are provided

37. Surgical procedures
38. Dental treatment under general anaesthesia or sedation
39. Use of certain techniques or technology

PART V

ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT
MEDICAL AGENCIES

40. Independent medical agencies

PART VI

MISCELLANEOUS

41. Compliance with regulations
42. Offences

SCHEDULES

- Schedule 1. Information to be included in the statement of

- Schedule 2. Information and documents required in respect of persons seeking to carry on, manage or work at an establishment or agency
- Schedule 3. Part I – Period for which medical records must be retained
Part II – Records to be maintained for inspection

The Department of Health, Social Services and Public Safety, in exercise of powers conferred on it by Articles 2(2), (7) to (9), 23(1), (2)(a) to (d), (f) to (j) (3), (5), (7)(a) to (h), (j) and (k), 25(1), 30, 31(1), 32 and 48(2) of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2004(a) and of all other powers enabling it in that behalf, having consulted such persons as it considers appropriate as required by Article 23(8) of that Order, hereby makes the following Regulations:

PART I GENERAL

Citation, commencement and extent

1. These Regulations may be cited as the Independent Health Care Regulations (Northern Ireland) 2005 and shall come into operation on 1st April 2005.

Interpretation

2.—(1) In these Regulations –

“agency” means an independent medical agency;

“dentist” means dental practitioner;

“establishment” means an independent hospital, or an independent clinic;

“ethics committee” has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004(b);

“Fire Authority” means the Fire Authority for Northern Ireland within the meaning of the Fire Services (Northern Ireland) Order 1984(c);

“general practitioner” means a medical practitioner providing primary medical services;

“health care professional” means a person who is registered as a member of any profession which is regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 or who is a clinical psychologist or child psychotherapist(d);

“medical device” has the same meaning as in the Medical Devices Regulations 2002(e);

“the Order” means the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003;

“the 1972 Order” means the Health and Personal Social Services (Northern Ireland) Order 1972(f);

“organisation” means a body corporate or any unincorporated association other than a partnership;

“patient”, in relation to any establishment or agency, means a person for whom treatment is provided in or for the purposes of the establishment, or for the purposes of the agency;

(a) S.I. 2003/431 (N.I. 9)

(b) S.I. 2004/1031

(c) S.I. 1984/1821 (N.I. 11)

(d) 2002 c. 17

(e) S.I. 2002/618

(f) S.I. 1972/1265 (N.I. 14)

“patient’s guide” means the guide compiled in accordance with regulation 8;

“practising privileges” in relation to a medical practitioner, refers to the grant to a person who is not employed in an independent hospital of permission to practise in that hospital;

“registered manager”, in relation to an establishment or agency, means a person who is registered under Part III of the Order as the manager of the establishment or agency;

“registered person”, in relation to an establishment or agency, means any person who is the registered provider or the registered manager of the establishment or agency;

“registered provider” in relation to an establishment or agency, means a person who is registered under Part III of the Order as the person carrying on the establishment or agency;

“responsible individual” shall be construed in accordance with regulation 10(2)(c)(i);

“statement of purpose” means the written statement compiled in accordance with regulation 7;

“treatment” includes palliative care and nursing and listed services within the meaning of Article 2 of the Order.

(2) In these Regulations, references to employing a person include employing a person whether under a contract of service or a contract for services.

Exceptions to the definition of independent hospital

3. For the purposes of Article 2 of the Order, establishments of the following descriptions are excepted from being independent hospitals –

- (a) an establishment which is a hospital by virtue of Article 2(2) of the Order solely because its main purpose is to provide medical or psychiatric treatment for illness or mental disorder but which provides no overnight beds for patients;
- (b) an establishment which is a service hospital within the meaning of section 13(9) of the Armed Forces Act 1981(a);
- (c) an establishment which is, or forms part of, a prison, within the meaning of the Prison Act (Northern Ireland) 1953(b) or a Remand Centre or Young Offenders Centre within the meaning of the Treatment of Offenders Act (Northern Ireland) 1968(c);
- (d) an establishment which is an independent clinic by virtue of regulation 5;
- (e) an establishment (not being a hospital which is vested in the Department or managed by an HSS trust) which has as its sole or main purpose the provision by a general practitioner of primary medical services; and such an establishment shall not become an independent hospital as a result of the provision of listed services to a patient by such a general practitioner;
- (f) the private residence of a patient in which treatment is provided to such patient, but to no one else;
- (g) sports grounds and gymnasia where health professionals provide treatment to persons taking part in sporting activities and events; and
- (h) a surgery or consulting room, not being part of a hospital, where a medical practitioner provides medical services solely under arrangements made on behalf of the patients by their employer or another person.

Prescribed techniques or technology

4.—(1) Subject to paragraph (2), for the purposes of Article 2 of the Order, “listed services” include treatment using any of the following techniques or technology –

- (a) a Class 3B or Class 4 laser product, as defined in Part I of British Standard EN 60825-1 (Radiation safety of laser products and systems)(d);

(a) 1981 c. 55

(b) 1953 c. 18

(c) 1968 c. 29

(d) Copies of BS EN 60825-1 may be obtained from BSI Customer Services, 389 Chiswick Road, London W4 4AL

- (b) an intense light, being broadband non-coherent light which is filtered to produce a specified range of wavelengths; such filtered radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues;
- (c) endoscopy; and
- (d) in vitro fertilisation techniques, being treatment services for which a licence may be granted under paragraph 1 of Schedule 2 to the Human Fertilisation and Embryology Act 1990(a).

(2) Listed services shall not include treatment using the following techniques or technology –

- (a) treatment for the relief of muscular and joint pain using an infra-red heat treatment lamp;
- (b) treatment using a Class 3B laser where such treatment is carried out by or under the supervision of a health care professional; and
- (c) the use of an apparatus (not being an apparatus falling within paragraph (1)(b), for acquiring an artificial suntan, consisting of a lamp or lamps emitting ultraviolet rays.

(3) Paragraph (7) of Article 2 of the Order shall be modified by adding at the end of subparagraph (d) (cosmetic surgery) the following –

“other than –

- (i) ear and body piercing;
- (ii) tattooing;
- (iii) the subcutaneous injection of a substance into the skin for cosmetic purposes; and
- (iv) the removal of hair roots or small blemishes on the skin by the application of heat using an electric current.”

Meaning of independent clinic

5.—(1) For the purposes of the definition of independent clinic under Article 2(2) of the Order, establishment of the following kinds are prescribed –

- (a) a walk-in centre, in which one or more medical practitioners provide services of a kind which, if provided in pursuance of the 1972 Order, would be provided as primary medical services; and
- (b) a surgery or consulting room in which a medical practitioner who provides no services in pursuance of the 1972 Order provides medical services of any kind (including psychiatric treatment) otherwise than under arrangements made on behalf of the patients by their employer or another person.

(2) Where two or more medical practitioners use different parts of the same premises as a surgery or consulting room, or use the same surgery or consulting room at different times, each of the medical practitioners shall be regarded as carrying on a separate independent clinic unless they are in practice together.

Exception of undertaking from the definition of independent medical agency

6. For the purposes of the Order any undertaking which consists of the provision of medical services by a medical practitioner solely under arrangements made on behalf of the patients by their employer or another person shall be excepted from being an independent medical agency.

Statement of purpose

7.—(1) The registered person shall compile in relation to the establishment or agency written statement which shall consist of a statement as to the matters listed in Schedule 1.

(2) The registered person shall supply a copy of the statement of purpose to the Regulation and Improvement Authority and shall make the statement available for inspection by every patient and any person acting on behalf of a patient.

(a) 1990 c. 37

(3) Nothing in regulation 15(1) or 25(1) and (2) shall require or authorise the registered person to contravene, or not to comply with –

- (a) any other provision of these Regulations; or
- (b) the conditions for the time being in operation in relation to the registration of the registered person under Part III of the Order.

Patient's guide

8.—(1) The registered person shall produce a written guide to the establishment or agency which shall consist of –

- (a) a summary of the statement of purpose;
- (b) the terms and conditions in respect of services to be provided for patients, including as to the amount and method of payment of charges for all aspects of their treatment;
- (c) a standard form of contract for the provision of services and facilities by the registered provider to patients;
- (d) a summary of the complaints procedure established under regulation 23;
- (e) a summary of the results of the consultation conducted in accordance with regulation 17(3);
- (f) the address and telephone number of the Regulation and Improvement Authority; and
- (g) the most recent inspection report prepared by the Regulation and Improvement Authority or information as to how a copy of that report may be obtained.

(2) The registered person shall supply a copy of the patient's guide to the Regulation and Improvement Authority, and shall make the patient's guide available for inspection by every patient and any person acting on behalf of a patient.

Review of statement of purpose and patient's guide

9. The registered person shall –

- (a) keep under review and, where appropriate, revise the statement of purpose, and the content of the patient's guide; and
- (b) notify the Regulation and Improvement Authority of any such revision.

PART II

REGISTERED PERSONS

Fitness of registered person provider

10.—(1) A person shall not carry on an establishment or agency unless he is fit to do so.

(2) A person is not fit to carry on an establishment or agency unless the person –

- (a) is an individual, who carries on the establishment or agency –
 - (i) otherwise than in partnership with others, and he satisfies the requirements set out in paragraph (3);
 - (ii) in partnership with others, and he and each of his partners satisfies the requirements set out in paragraph (3);
- (b) is a partnership, and each of the partners satisfies the requirements set out in paragraph (3);
- (c) is an organisation and –
 - (i) the organisation has given notice to the Regulation and Improvement Authority of the name, address and position in the organisation of an individual who is a director, manager, secretary or other officer of the organisation and is responsible for supervising the management of the establishment or agency; and
 - (ii) that individual satisfies the requirements set out in paragraph (3).

- (3) The requirements are that –
 - (a) he is of integrity and good character;
 - (b) he is physically and mentally fit to carry on the establishment or agency; and
 - (c) full and satisfactory information is available in relation to him in respect of each of the matters specified in Schedule 2.
- (4) A person shall not carry on an establishment or agency if –
 - (a) he has been adjudged bankrupt or sequestration of his estate has been awarded and (in either case) he has not been discharged and the bankruptcy order has not been annulled or rescinded; or
 - (b) he has made a composition or arrangement with his creditors and has not been discharged in respect of it.

Appointment of manager

- 11.**—(1) The registered provider shall appoint an individual to manage an establishment or agency if –
- (a) there is no registered manager in respect of the establishment or agency; and
 - (b) the registered provider –
 - (i) is an organisation or a partnership;
 - (ii) is not a fit person to manage an establishment or agency; or
 - (iii) is not, or does not intend to be, in full-time day-to-day charge of the establishment or agency.
- (2) Where the registered provider appoints a person to manage the establishment or agency, he shall forthwith give notice to the Registration and Inspection Authority of –
- (a) the name of the person so appointed; and
 - (b) the date on which the appointment is to take effect.

Fitness of registered manager

- 12.**—(1) A person shall not manage an establishment or agency unless he is fit to do so.
- (2) A person is not fit to manage an establishment or agency unless –
- (a) he is of integrity and good character;
 - (b) having regard to the size of the establishment or agency, the statement of purpose, and the number and needs of the patients –
 - (i) he has the qualifications, skills and experience necessary to manage the establishment or agency; and
 - (ii) he is physically and mentally fit to do so; and
 - (c) full and satisfactory information is available in relation to him in respect of each of the matters specified in Schedule 2.

Registered person: general requirements

- 13.**—(1) The registered provider and the registered manager shall, having regard to the size of the establishment or agency, the statement of purpose and the number and needs of the patients, carry on or (as the case may be) manage the establishment or agency with sufficient care, competence and skill.
- (2) If the registered person provider is –
- (a) an individual, he shall undertake;
 - (b) an organisation, it shall ensure that the responsible individual undertakes;
 - (c) a partnership, it shall ensure that one of the partners undertakes,
- from time to time such training as is appropriate to ensure that he has the skills necessary for carrying on the establishment or agency.

(3) The registered manager shall undertake from time to time such training as is appropriate to ensure that he has the skills necessary for managing the establishment or agency.

Registered person: notification of offences

14. Where the registered person or the responsible individual is convicted of any criminal offence whether in Northern Ireland or elsewhere, he shall forthwith give notice in writing to the Regulation and Improvement Authority of –

- (a) the date and place of the conviction;
- (b) the offence of which he was convicted; and
- (c) the penalty imposed on him in respect of the offence.

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(a).

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.

(a) S.I. 2004/1031

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 subparagraphs (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.

PART IV

ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT HOSPITALS

PATHOLOGY SERVICES, RESUSCITATION AND TREATMENT OF CHILDREN IN INDEPENDENT HOSPITALS

Application of regulations 34 to 36

33.—(1) Regulations 34 to 36 apply to independent hospitals of the following kinds –

- (a) those defined in Article 2(2) of the Order except establishments excepted by regulation 4(2); and
- (b) those in which medical treatment, including cosmetic surgery, is provided under anaesthesia or sedation.

(2) Regulation 34 also applies to any establishment or agency which provides pathology services.

Pathology services

34. The registered person shall ensure that –

- (a) an adequate range of pathology services is available to meet the needs of the independent hospital;
- (b) those services are provided to an appropriate standard;
- (c) appropriate arrangements are made for the collection, and (where pathology services are provided outside the hospital) transportation of pathology specimens; and
- (d) the patient from whom a specimen was taken and such specimen, is identifiable at all times.

Resuscitation

35.—(1) The registered person shall prepare and implement a written statement of the policies to be applied and the procedures to be followed in the hospital in relation to resuscitation of patients, and shall review such statement annually.

(2) The registered person shall ensure that policies and procedures implemented in accordance with paragraph (1) –

- (a) take proper account of the right of all patients who are competent to do so to give or withhold consent to treatment;
- (b) are available on request to every patient and any person acting on behalf of a patient; and
- (c) are communicated to and understood by all employees and all medical practitioners with practising privileges who may be involved in decisions about resuscitation of a patient.

Treatment of children

36. The registered person shall ensure that, where a child is treated in an independent hospital –

- (a) he is treated in accommodation which is separate from accommodation in which adult patients are treated;
- (b) particular medical, physical, psychological, social, educational and supervision needs arising from his age are met;
- (c) his treatment is provided by persons who have appropriate qualifications, skills and experience in the treatment of children;
- (d) his parents are kept fully informed of his condition and so far as is practicable consulted about all aspects of his treatment, except where the child is himself competent to consent to treatment and does not wish his parents to be so informed and consulted.

INDEPENDENT HOSPITALS IN WHICH CERTAIN LISTED SERVICES ARE PROVIDED

Surgical procedures

37.—(1) Where medical treatment (including cosmetic surgery) is provided under anaesthesia or sedation in an independent hospital, the registered person shall ensure that –

- (a) each operating theatre is designed, equipped and maintained to an appropriate standard for the purposes for which it is to be used;
- (b) all surgery is carried out by, or under the direction of, a suitable qualified, skilled and experienced medical practitioner;
- (c) an appropriate number of suitably qualified, skilled and experienced employees are in attendance during each surgical procedure; and
- (d) the patient receives appropriate treatment –
 - (i) before administration of an anaesthetic or sedation;
 - (ii) whilst undergoing a surgical procedure;
 - (iii) during recovery from general anaesthesia; and
 - (iv) post-operatively.

(2) The registered person shall ensure that before a patient consents to any surgery offered by the independent hospital, he has received clear and comprehensive information about the procedure and any risks associated with it.

(3) In the case of a patient who is not competent to consent to surgery, the information mentioned in paragraph (2) shall, wherever possible, be provided to his representative.

Dental treatment under general anaesthesia or sedation

38. Where the treatment provided in an independent hospital includes dental treatment under general anaesthesia or sedation, the registered person shall ensure that –

- (a) the dentist and any employees assisting him are suitable, qualified, skilled and experienced to deal with any emergency which occurs during or as a result of the general anaesthesia, sedation or treatment; and
- (b) adequate facilities, drugs and equipment are available to deal with any such emergency.

Use of certain techniques or technology

39.—(1) The registered person shall ensure that no Class 3B or Class 4 laser or intense light source (within the meaning of regulation 4(1)), is used in or for the purposes of an independent hospital unless that hospital has in place a professional protocol drawn up by a trained and experienced medical practitioner or dentist from the relevant discipline in accordance with which treatment is to be provided, and is so provided.

(2) The registered person shall ensure that such a laser or intense light source is used in or for the purposes of the hospital only by a person who has undertaken appropriate training and has demonstrated an understanding of –

- (a) the correct use of the equipment in question;
- (b) the risks associated with using a laser or intense light source;
- (c) its biological and environmental effects;
- (d) precautions to be taken before and during use of a laser or intense light source; and
- (e) action to be taken in the event of an accident, emergency, or other adverse incident.

PART V

ADDITIONAL REQUIREMENTS APPLYING TO INDEPENDENT MEDICAL AGENCIES

Independent medical agencies

40. The registered person shall ensure that the register of patients to be maintained in relation to an independent medical agency under Part II of Schedule 3 includes the name of the medical practitioner by whom each patient is treated.

PART VI

MISCELLANEOUS

Compliance with regulations

41. Where there is more than one registered person in respect of an establishment or agency, anything which is required under these Regulations to be done by the registered person shall, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Offences

42.—(1) A contravention, or failure to comply with, any of the provisions of regulations 7, 8, 14, 15, 16(1) to (4), 17 to 32 and 34 to 40 shall be an offence.

(2) The Regulation and Improvement Authority shall not bring proceedings against a person in respect of any contravention of these regulations unless –

- (a) subject to paragraph (4), he is a registered person;
- (b) notice has been given to him in accordance with paragraph (3);
- (c) the period specified in the notice beginning with, and including the date of the notice has expired; and

(d) the person contravenes any of the provisions of the regulations mentioned in the notice.

(3) Where the Regulation and Improvement Authority considers that the registered person has contravened any of the provisions of the regulations mentioned in paragraph (1), it may serve a notice on the registered person specifying –

- (a) in what respect in its opinion the registered person has contravened the requirements of any of the regulations;
- (b) what action, in the opinion of the Regulation and Improvement Authority, the registered person should take so as to comply with any of these regulations; and
- (c) the period, not exceeding three months beginning on and including the date on which the notice is given, within which the registered person should take action.

(4) The Regulation and Improvement Authority may bring proceedings against a person who was once, but no longer is a registered person, in respect of a failure to comply with regulation 21 and for this purpose, references in paragraphs (2) and (3) to a registered person shall be taken to include such a person.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 25th March 2005.

(L.S.)

N. McCann

Senior Officer of the Department of Health, Social Services and Public Safety

SCHEDULE 1

Regulation 7

INFORMATION TO BE INCLUDED IN THE STATEMENT OF PURPOSE

1. The aims and objectives of the establishment or agency.
2. The name and address of the registered provider and of any registered manager.
3. The relevant qualifications and experience of the registered provider and any registered manager.
4. The number, relevant qualifications and experience of the staff working in the establishment, or for the purposes of the agency.
5. The organisational structure of the establishment or agency.
6. The kinds of treatment and any other services provided for the purposes of the establishment or agency, the range of needs which those services are intended to meet and the facilities which are available for the benefit of patients.
7. The arrangements made for consultation with patients about the operation of the establishment or agency.
8. The arrangements made for contact between any in-patients and their relatives, friends and representatives.
9. The arrangements for dealing with complaints.
10. The arrangements for respecting the privacy and dignity of patients.

SCHEDULE 2

Regulations 10(3), 12(2)
and 19(2)

INFORMATION REQUIRED IN RESPECT OF PERSONS SEEKING TO CARRY ON, MANAGE OR WORK AT AN ESTABLISHMENT OR AGENCY

1. Positive proof of identity including a recent photograph.
2. Either –
 - (a) where a certificate is required for a purpose relating to registration under Part III of the Order, or the position falls within section 115(3) or (4) of the Police Act 1997(a), an enhanced criminal record certificate issued under section 115 of that Act; or
 - (b) in any other case, a criminal certificate issued under section 113 of that Act,including, where applicable, the matters specified in section 113(3EA) and 115(6EA) of that Act(b) and the following provisions once they are in force, namely section 113(3EC)(a) and (b) and section 115(6EB)(a) and (b) of that Act(c).
3. Two written references relating to the person, including a reference from the person's present or most recent employers, if any.
4. Where a person has previously worked in a position whose duties which involved work with children or vulnerable adults, verification, so far as reasonably practicable, of the reason why he ceased to work in that position.
5. Documentary evidence of any relevant qualifications or accredited training.
6. A full employment history, together with a satisfactory written explanation of any gaps in employment.

(a) 1997 c. 50

(b) Sections 113(3EA) and 115(6EA) are inserted by S.I. 2003/417 (N.I. 4) – Article 17

(c) Sections 113(3EC) and 115(6EB) are inserted by S.I. 2003/417 (N.I. 4) – Article 47

7. Where he is a health care professional, details of his registration with the body (if any) responsible for regulation of members of the health care profession in question.

8. Details of any criminal offences –

(a) of which the person has been convicted, including details of any convictions which are spent within the meaning of Article 3 of the Rehabilitation of Offenders (Northern Ireland) Order 1978^(a) and which may be disclosed by virtue of the Rehabilitation of Offenders (Exceptions) Order (Northern Ireland 1979)^(b); or

(b) in respect of which he has been cautioned by a constable and which, at the time the caution was given, he admitted.

9. Confirmation that he is physically and mentally fit to fulfil his duties and responsibilities.

10. Details of any professional indemnity insurance.

SCHEDULE 3

Regulation 21(1), (3)

PART I

PERIOD FOR WHICH MEDICAL RECORDS MUST BE RETAINED

<i>Type of patient</i>	<i>Minimum period of retention</i>
(a) Patient who was under the age of 17 at the date on which the treatment to which the records refer was concluded.	Until the patient's 25th birthday.
(b) Patient who was aged 17 at the date on which the treatment to which the records refer was concluded.	Until the patient's 26th birthday.
(c) Patient who died before attaining the age of 18.	A period of 8 years beginning on the date of the patient's death.
(d) Patient whose records relate to treatment by a general practitioner.	A period of 10 years beginning on the date of the last entry.
(e) All other cases.	A period of 8 years beginning on the date of the last entry in the record.

PART II

RECORDS TO BE MAINTAINED FOR INSPECTION

1. A register of patients, including –

(a) the name, address, telephone number, date of birth and marital status of each patient;

(b) the name, address and telephone number of the patient's next of kin or any person authorised by the patient to act on his behalf;

(c) the name, address and telephone number of the patient's general practitioner;

(d) where the patient is a child, the name and address of the school which he attends or attended before admission to an establishment;

(e) the name and address of any body which arranged the patient's admission or treatment;

(f) the date on which the patient was admitted to an establishment or first received treatment provided for the purposes of an establishment or agency;

(g) the nature of the treatment for which the patient was admitted or which he received;

(h) where the patient has been an in-patient in an independent hospital, the date of his discharge;

(a) S.I. 1978/1908 (N.I. 27)

(b) S.R. 1979 No. 195; amended by the Osteopaths Act 1993 (c. 21) section 39; the Chiropractors Act 1994 (c. 17) section 40; S.R. 1987 No. 393, S.R. 2001 No. 248, and S.R. 2001 No. 400. The relevant provisions of the Osteopaths Act 1993 and the Chiropractors Act 1994 are repealed by section 133 of, and Schedule 10 to, the Police Act 1997 (c. 50)

- (i) if the patient has been transferred to a hospital (including a hospital vested in the Department or managed by an HSS trust), the date of the transfer, the reasons for it and the name of the hospital to which the patient was transferred;
 - (j) if the patient dies whilst in an establishment or during treatment provided for the purposes of an establishment or agency, the date, time and cause of his death.
2. A register of all surgical operations performed in an establishment or by an agency, including –
- (a) the name of the patient on whom the operation was performed;
 - (b) the nature of the surgical procedure and the date on which it took place;
 - (c) the name of the medical practitioner or dentist by whom the operation was performed;
 - (d) the name of the anaesthetist in attendance;
 - (e) the name and signature of the person responsible for checking that all needles, swabs and equipment used during the operation have been recovered from the patient;
 - (f) details of all implanted medical devices, except where this would entail the disclosure of information contrary to the provisions of section 33(5) of the Human Fertilisation and Embryology Act 1990^(a) (restrictions on disclosure of information).
3. A register of each occasion on which a technique or technology to which regulation 39 applies has been used; including –
- (a) the name of the patient in connection with whose treatment the technique or technology was used;
 - (b) the nature of the technique or technology in question and the date on which it was used; and
 - (c) the name of the person using it.
4. A register of all mechanical and technical equipment used for the purposes of treatment provided by the establishment or agency including –
- (a) the date of purchase of the equipment;
 - (b) the date of installation of the equipment;
 - (c) details of maintenance of the equipment and the dates on which maintenance work was carried out.
5. A register of all events which must be notified to the Regulation and Improvement Authority in accordance with regulation 28.
6. A register of each person employed in or for the purposes of the establishment, or for the purposes of the agency and each medical practitioner to whom practising privileges have been granted, including –
- (a) his name and date of birth;
 - (b) details of his position in the establishment or agency;
 - (c) dates of employment; and
 - (d) in respect of a health care professional, details of his professional qualifications and registration with his professional regulatory body.
7. A written record of suspected, alleged or actual incidents of abuse including details of the investigation, the outcome and action taken.
8. A record of all documentation relating to the recruitment process.
9. A record of all training and professional development activities completed by staff.
10. A record of the annual appraisal for each member of staff.

^(a) 1997 c. 37

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (“the Order”). Part II of the Order establishes the Northern Ireland Health and Personal Social Services Regulation and Improvement Authority (“the Regulation and Improvement Authority”) and Part III provides for the registration and inspection of establishments and agencies, including independent health care establishments and agencies, by the Regulation and Improvement Authority. It also provides powers for regulations governing the conduct of establishments and agencies.

Regulation 4 provides that “listed services” include treatment using the prescribed techniques and technology set out in regulation 4(1). Regulation 4(2) then excepts certain techniques and technology from being listed services, and regulation 3 excludes certain establishments from the definition of an independent hospital under Article 2 of the Order. These include establishments providing medical or psychiatric treatment but which have no overnight beds for patients, establishments which are service hospitals under the Armed Forces Act 1981, or which are establishments catering for offenders. In addition, independent clinics (as defined in these Regulations) are excluded, as are establishments where general practitioners provide HPSS services, but where there may be a small minority of private patients who also receive treatment. The private residence of a patient is also excluded provided that treatment is provided there only to that patient, as are surgeries and consulting rooms (which are separate from a hospital) which provide medical services under arrangements made on behalf of patients by their employers or others, and sports grounds and gymnasias where treatment is given to those taking part in sporting activities and events.

Regulation 4(3) modifies the definition of cosmetic surgery for the purpose of Article 2(7) of the Order.

Regulation 5 defines the meaning of the term “independent clinic” and regulation 6 excepts certain establishments from being an independent medical agency.

By regulation 7, each establishment or agency must have a statement of purpose consisting of the matters set out in Schedule 1, and a patients’ guide to the establishment or agency must be carried on in a manner which is consistent with the statement of purpose.

Regulations 10 to 14 make provision about the fitness of the persons carrying on and managing an establishment or agency and require satisfactory information to be obtained in relation to the matters prescribed in Schedule 2. Where the provider is an organisation, it must nominate a responsible individual in respect of whom this information must be available (regulation 10). Regulation 11 prescribes the circumstances where a manager must be appointed for the establishment or agency, and regulation 13 imposes general requirements in relation to the proper conduct of the establishment or agency, and the need for appropriate training.

Part III makes provision about the conduct of establishments or agencies, in particular about the quality of the services to be provided in an establishment or agency, including matters relating to privacy, dignity and religious observance, the staffing of the establishment or agency and the fitness of workers and about complaints and record keeping (regulation 21 and Schedule 3). Provision is also made about the suitability of premises and the fire precautions to be taken and the management of establishments and agencies. The registered provider is required to visit the establishment or agency as prescribed (regulation 26), and regulation 27 imposes requirements relating to the financial viability of the establishment or agency. Regulations 28 to 32 deal with the giving of notices to the Regulation and Improvement Authority.

Part IV and Schedule 4 set out additional requirements that apply to independent hospitals, and Part V sets out additional requirements applying to independent medical agencies.

Part VI deals with miscellaneous matters. In particular, regulation 42 provides for offences. A breach of regulations 7, 8, 14, 15, 16(1) to (4), 17 to 32 and 34 to 40 may found an offence on the part of the registered person. However, no prosecution may be brought unless the Regulation and Improvement Authority has given the registered person a notice which sets out in what respect it is alleged he is not complying with a regulation, and what action, and by when the Regulation and Improvement Authority considers it is necessary in order to comply with the regulation.

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