

2004 No. 1768

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Complaints) Regulations 2004

<i>Made</i> - - - -	<i>9th July 2004</i>
<i>Laid before Parliament</i>	<i>9th July 2004</i>
<i>Coming into force</i> - -	<i>30th July 2004</i>

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The Secretary of State for Health, in exercise of the powers conferred on him by sections 17(1) and 18(3) of the National Health Service Act 1977^(a) and sections 113(1), (3) and (4), 115(1),(2), (4), (5) and (6) and 195(1), (2) and (4) of the Health and Social Care (Community Health and Standards) Act 2003^(b) hereby makes the following Regulations:

**PART I
INTRODUCTION**

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Complaints) Regulations 2004 and come into force on 30th July 2004.

(2) These Regulations apply in relation to England.

Interpretation

2.—(1) In these Regulations—

“the 1977 Act” means the National Health Service Act 1977;

“the 2003 Act” means the Health and Social Care (Community Health and Standards) Act 2003;

“complainant” in Part II means any person who makes or has made a complaint in accordance with regulation 9 to an NHS body and in Part III means any person who has made a complaint in accordance with regulation 14 or 15 to the Healthcare Commission;

“complaints manager” means the person designated in accordance with regulation 5;

“default contract” means a contract entered into under article 13 of the General Medical Services Transitional and Consequential Provisions Order 2004 (c);

“disciplinary proceedings” means any procedure for disciplining employees adopted by an NHS body;

“former complaints provisions” has the meaning given in regulation 23;

“general medical services contractor” means a person who has entered into a general medical services contract with a Primary Care Trust in accordance with section 28Q of the 1977 Act;

“the Healthcare Commission” means the Commission for Healthcare, Audit and Inspection established under section 41 of the 2003 Act;

“health care professional” means a person who is a member of a profession which is regulated by a health regulatory body;

(a) 1977 c. 49. Section 17 was amended by the Health Authorities Act 1995 (c.17), sections 2(1) and 8 and paragraph 8 of Schedule 1.

(b) 2003 c. 43.

(c) S.I. 2004/433.

“health regulatory body” means a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(a);

“Health Service Commissioner” means the person appointed Health Service Commissioner for England in accordance with section 1 of, and Schedule 1 to, the Health Service Commissioners Act 1993(b);

“independent provider” means a person or body, including a voluntary organisation but excluding an NHS foundation trust, which is providing services under arrangements made with an NHS body in accordance with section 16CC(2) or section 23 of the 1977 Act;

“Independent Regulator” means the Independent Regulator of NHS Foundation Trusts established under section 2 of the 2003 Act;

“NHS body” means a Strategic Health Authority, an NHS Trust which operates from premises wholly or mainly in England, a Primary Care Trust and a Special Health Authority to which section 2 of the Health Service Commissioners Act 1993 applies(c);

“NHS contract” has the meaning given in section 4 of the National Health Service and Community Care Act 1990(d);

“NHS foundation trust” has the meaning given in section 1 of the 2003 Act;

“patient” in regulation 8 means a person who is receiving or has received services from an NHS body or an independent provider and in regulation 15 means a person who is receiving or has received services from an NHS foundation trust;

“patients’ forum” means a patients’ forum established in accordance with section 15 of the National Health Service Reform and Health Care Professions Act 2002;

“primary care services” means services provided by a primary care provider;

“primary care provider” has the meaning given in paragraph (2);

“Primary Care Trust” means a body established under section 16A of the 1977 Act;

“relevant patients’ forum” in relation to an NHS trust or a Primary Care Trust, means the patients’ forum established for the NHS trust or Primary Care Trust;

“relevant Primary Care Trust” means, in relation to a primary care provider, the Primary Care Trust which has made arrangements with that primary care provider for the provision of primary care services;

“relevant Strategic Health Authority” means, in relation to an NHS trust or a Primary Care Trust, the Strategic Health Authority in whose area the NHS trust or Primary Care Trust wholly or mainly exercises its functions;

“staff” means any person who is employed by, or engaged to provide services to, an NHS body;

“transitional agreement” means an agreement which, by virtue of article 58 of the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004(e), is deemed to have been made under section 28C of the 1977 Act and which has not been varied in accordance with article 59 of that Order; and

“working day” means any day other than a Saturday, a Sunday, Christmas Day, Boxing Day, Good Friday or a day which is a bank holiday in England under the Banking and Financial Dealings Act 1971(f).

(2) A primary care provider means—

- (a) a general medical services contractor;
- (b) a person who has entered into a default contract with a Primary Care Trust;

(a) 2002 c. 17.

(b) 1993 c.46.

(c) 1993 c.46. The Special Health Authorities to which the Health Service Commissioners Act 1993 applies are the Family Health Services Appeal Authority (see S.I. 1995/753), the Mental Health Act Commission (see S.I. 1983/1114), the National Blood Authority (see S.I. 1994/2954), and the Health Protection Agency, the National Clinical Assessment Authority, the National Health Service Information Authority, the National Health Service Logistics Authority, the Retained Organs Commission, and United Kingdom Transplant (see S.I. 2004/1119).

(d) 1990 c. 19.

(e) S.I. 2004/865.

(f) 1971 c.80.

- (c) a person who provides primary medical services in accordance with arrangements made either under section 28C of the 1977 Act or under a transitional agreement;
- (d) a dental practitioner who is providing general dental services in accordance with arrangements made under section 35 of the 1977 Act;
- (e) a dental practitioner who provides personal dental services in accordance with a pilot scheme under section 1 of the Primary Care Act 1997 (a);
- (f) an ophthalmic optician or an ophthalmic medical practitioner who provides general ophthalmic services in accordance with arrangements made under section 38 of the 1977 Act;
- (g) a person who provides pharmaceutical services in accordance with arrangements made under section 41 of the 1977 Act; and
- (h) a person who provides local pharmaceutical services in accordance with a pilot scheme under section 28 of, and Schedule 2 to, the Health and Social Care Act 2001(b).

PART II

HANDLING AND CONSIDERATION OF COMPLAINTS BY NHS BODIES

Arrangements for the handling and consideration of complaints

3.—(1) Each NHS body must make arrangements in accordance with these Regulations for the handling and consideration of complaints.

(2) The arrangements must be accessible and such as to ensure that complaints are dealt with speedily and efficiently, and that complainants are treated courteously and sympathetically and as far as possible involved in decisions about how their complaints are handled and considered.

(3) The arrangements must be in writing and a copy must be given, free of charge, to any person who makes a request for one.

(4) Where an NHS trust or a Primary Care Trust makes arrangements for the provision of services with an independent provider, it must ensure that the independent provider has in place arrangements for the handling and consideration of complaints about any matter connected with its provision of services as if these Regulations applied to it.

Responsibility for complaints arrangements

4. Each NHS body must designate one of its members, or in the case of an NHS trust a member of its board of directors, to take responsibility for ensuring compliance with the arrangements made under these Regulations and that action is taken in the light of the outcome of any investigation.

Complaints manager

5.—(1) Each NHS body must designate a person, in these Regulations referred to as a complaints manager, to manage the procedures for handling and considering complaints and in particular—

- (a) to perform the functions of the complaints manager under this Part; and
- (b) to perform such other functions in relation to complaints as the NHS body may require.

(2) The functions of the complaints manager may be performed by him or by any person authorised by the NHS body to act on his behalf.

Complaints to NHS bodies

6. Subject to regulation 7, a complaint to an NHS body may be about any matter reasonably connected with the exercise of its functions including in particular, in the case of an NHS trust or Primary Care Trust, any matter reasonably connected with—

(a) 1997 c. 46.
(b) 2001 c. 15.

- (a) its provision of health care or any other services, including in the case of a Primary Care Trust, its provision of primary medical services under section 16CC of the 1977 Act; and
- (b) the function of commissioning health care or other services under an NHS contract or making arrangements for the provision of such care or other services with an independent provider or with an NHS foundation trust.

Matters excluded from consideration under the arrangements

7. The following complaints are excluded from the scope of the arrangements required under this Part —

- (a) a complaint made by an NHS body which relates to the exercise of its functions by another NHS body;
- (b) a complaint made by a primary care provider which relates either to the exercise of its functions by an NHS body or to the contract or arrangements under which it provides primary care services;
- (c) a complaint made by an employee of an NHS body about any matter relating to his contract of employment;
- (d) a complaint made by an independent provider or an NHS foundation trust about any matter relating to arrangements made by an NHS body with that independent provider or NHS foundation trust;
- (e) a complaint which relates to the provision of primary medical services in accordance with arrangements made by a Primary Care Trust with a Strategic Health Authority under section 28C of the 1977 Act or under a transitional agreement;
- (f) a complaint which is being or has been investigated by the Health Service Commissioner;
- (g) a complaint arising out of an NHS body’s alleged failure to comply with a data subject request under the Data Protection Act 1998(a) or a request for information under the Freedom of Information Act 2000(b);
- (h) a complaint about which the complainant has stated in writing that he intends to take legal proceedings; and
- (i) a complaint about which an NHS body is taking or is proposing to take disciplinary proceedings in relation to the substance of the complaint against a person who is the subject of the complaint.

Persons who may make complaints

8.—(1) A complaint may be made by—

- (a) a patient; or
- (b) any person who is affected by or likely to be affected by the action, omission or decision of the NHS body which is the subject of the complaint.

(2) A complaint may be made by a person (in these Regulations referred to as a representative) acting on behalf of a person mentioned in paragraph (1) in any case where that person—

- (a) has died;
- (b) is a child;
- (c) is unable by reason of physical or mental incapacity to make the complaint himself; or
- (d) has requested the representative to act on his behalf.

(3) In the case of a patient or person affected who has died or who is incapable, the representative must be a relative or other person who, in the opinion of the complaints manager, had or has a sufficient interest in his welfare and is a suitable person to act as representative.

(a) 1998 c. 29
 (b) 2000 c. 36.

(4) If in any case the complaints manager is of the opinion that a representative does or did not have a sufficient interest in the person's welfare or is unsuitable to act as a representative, he must notify that person in writing, stating his reasons.

(5) In the case of a child, the representative must be a parent, guardian or other adult person who has care of the child and where the child is in the care of a local authority or a voluntary organisation, the representative must be a person authorised by the local authority or the voluntary organisation.

(6) In these Regulations any reference to a complainant includes a reference to his representative.

Making a complaint

9.—(1) Where a person wishes to make a complaint under these Regulations, he may make the complaint to the complaints manager or any other member of the staff of the NHS body which is the subject of the complaint.

(2) A complaint may be made orally or in writing (including electronically) and—

(a) where it is made orally, the complaints manager must make a written record of the complaint which includes the name of the complainant, the subject matter of the complaint and the date on which it was made; and

(b) where it is made in writing, the complaints manager must make a written record of the date on which it was received.

(3) For the purposes of these Regulations where the complaint is made in writing it is treated as being made on the date on which it is received by the complaints manager or as the case may be, other member of the staff of the NHS body.

Time limit for making a complaint

10.—(1) Subject to paragraph (2) a complaint must be made within—

(a) six months of the date on which the matter which is the subject of the complaint occurred; or

(b) six months of the date on which the matter which is the subject of the complaint came to the notice of the complainant.

(2) Where a complaint is made after the expiry of the period mentioned in paragraph (1), the complaints manager may investigate it if he is of the opinion that—

(a) having regard to all the circumstances, the complainant had good reasons for not making the complaint within that period; and

(b) notwithstanding the time that has elapsed it is still possible to investigate the complaint effectively and efficiently.

Acknowledgement and record of complaint

11.—(1) The complaints manager must send to the complainant a written acknowledgement of the complaint within 2 working days of the date on which the complaint was made.

(2) Where a complaint was made orally, the acknowledgement must be accompanied by the written record mentioned in regulation 9(2)(a) with an invitation to the complainant to sign and return it.

(3) The complaints manager must send a copy of the complaint and his acknowledgement to any person identified in the complaint as the subject of the complaint.

(4) The acknowledgement sent to the complainant under paragraph (1) must include information about the right to assistance from the independent advocacy services provided under section 19A of the 1977 Act.

Investigation

12.—(1) The complaints manager must investigate the complaint to the extent necessary and in the manner which appears to him most appropriate to resolve it speedily and efficiently.

(2) The complaints manager may, in any case where he thinks it would be appropriate to do so and with the agreement of the complainant, make arrangements for conciliation, mediation or other assistance for

the purposes of resolving the complaint, and in any such case the NHS body must ensure that appropriate conciliation or mediation services are available.

(3) The complaints manager must take such steps as are reasonably practicable to keep the complainant informed about the progress of the investigation.

Response

13.—(1) The complaints manager must prepare a written response to the complaint which summarises the nature and substance of the complaint, describes the investigation under regulation 12 and summarises its conclusions.

(2) The response must be signed by the chief executive of the NHS body except in cases where for good reason the chief executive is not himself able to sign it, in which case it may be signed by a person acting on his behalf.

(3) Subject to paragraph (4), the response must be sent to the complainant within 20 working days beginning on the date on which the complaint was made or, where that is not possible, as soon as reasonably practicable.

(4) The response must notify the complainant of his right to refer the complaint to the Healthcare Commission in accordance with regulation 14.

(5) Copies of the response mentioned in paragraph (1) must be sent to any other person to whom the complaint was sent under regulation 11(3).

PART III

HANDLING AND CONSIDERATION OF COMPLAINTS BY THE HEALTHCARE COMMISSION

General complaints remit of the Healthcare Commission

14.—(1) In any case where—

- (a) a complainant is not satisfied with the result of an investigation—
 - (i) by an NHS body under regulation 12, or
 - (ii) by an independent provider, with whom an NHS trust or Primary Care Trust has made arrangements as mentioned in regulation 6, in accordance with its arrangements for the handling and consideration of complaints;
- (b) for any reason an investigation mentioned in paragraph (1)(a) has not been completed within 6 months of the date on which the complaint was made, or
- (c) a complaints manager has decided not to investigate a complaint on the grounds that it was not made within the time limit mentioned in regulation 10;

he may request the Healthcare Commission to consider the complaint in accordance with this Part.

(2) In any case where a person has made a complaint to a primary care provider and is not satisfied with the outcome of an investigation of his complaint by the primary care provider, in accordance with its procedures for the handling and investigation of complaints, he, or a person who acted as his representative in accordance with those procedures, may request the Healthcare Commission to consider the complaint in accordance with this Part(a).

(a) The complaints procedures which apply to primary care providers are contained either in regulations made under the appropriate provisions in the 1977 Act or in directions made under section 17 of the 1977 Act. See S.I. 2004/291, Schedule 6, paragraphs 92 to 98 for general medical services contracts; S.I. 2004/433, article 13(4)(b) for default contracts; S.I. 2004/627, Schedule 5, paragraphs 86 to 92 for persons providing primary medical services; S.I.1992/661 Schedule 2, paragraphs 31A to 31C for general dental services; the Directions concerning the implementation of pilot schemes for personal dental services 10th August 1998, paragraph 18 and Schedule 2 for personal dental services; S.I. 1986/975, Schedule 1, paragraph 8A for general ophthalmic services; S.I. 1992/662, Schedule 2, paragraphs 10A, 10B, 14 and 15 for pharmaceutical services and the Primary Care Trusts Preparation of Proposals and Implementation of Pilot Schemes (Local Pharmaceutical Services) Directions 2003, paragraph 16 and Schedule 1 for persons providing local pharmaceutical services.

(3) A request under paragraphs (1) or (2) may be made either orally or in writing (including electronically) and must be made within 2 months of, or where that is not possible, as soon as reasonably practicable after, the date on which the response mentioned in regulation 13, or, as the case may be, under the complaints arrangements of the primary care provider, was sent to the complainant.

Remit of Healthcare Commission in relation to complaints about NHS foundation trusts

15.—(1) Subject to paragraphs (2) to (7), where a person has made a complaint to an NHS foundation trust and either—

- (a) he is not satisfied with the outcome of any investigation of that complaint by the NHS foundation trust in accordance with any procedures it may have; or
- (b) the NHS foundation trust has no complaints procedures,

he may request the Healthcare Commission to consider the complaint in accordance with this Part.

(2) The Healthcare Commission's remit in relation to NHS foundation trusts is limited to consideration only of a complaint which—

- (a) is made by a patient; and
- (b) is reasonably connected with the provision of health care or other services to patients by or for the NHS foundation trust.

(3) The Healthcare Commission may not consider a complaint made under this regulation where the complaint—

- (a) is one about which the complainant has stated in writing that he intends to take legal proceedings;
- (b) is one about which the NHS foundation trust has stated in writing that it is taking or is proposing to take disciplinary proceedings in relation to the substance of the complaint against a person who is the subject of the complaint;
- (c) arises out of the NHS foundation trust's alleged failure to comply with a data subject request under the Data Protection Act 1998 or a request for information under the Freedom of Information Act 2000 ; or
- (d) which is being or has been investigated by the Health Service Commissioner.

(4) Where the Healthcare Commission consider that a complaint or any part of a complaint made under this regulation does not fall within paragraph (2), it must refer that complaint or part of a complaint to the Independent Regulator.

(5) The provisions in regulation 8 (2) to (6) (provision about representatives) apply to complaints made to the Healthcare Commission about NHS foundation trusts as if—

- (a) the reference in paragraph (2) to paragraph (1) of that regulation were a reference to paragraph (2) of this regulation; and
- (b) the references to the complaints manager in paragraphs (3) and (4) were references to the Healthcare Commission.

(6) A request under paragraph (1) must be made within 2 months of, or where that is not possible, as soon as reasonably practicable after, the date on which a response under the NHS foundation trust's complaints arrangements was sent to the complainant or, where there are no such arrangements, as soon as reasonably practicable.

(7) On receipt of a complaint about an NHS foundation trust, the Healthcare Commission must, within two working days and provided that it has the consent, which may be either express or implied, of the complainant, send a copy of the complaint to the Independent Regulator and invite his views on the complaint.

Decision on handling of complaint

16.—(1) On receipt of the complaint the Healthcare Commission must assess the nature and substance of the complaint and decide how it should be handled having regard to —

- (a) the views of the complainant;

- (b) the views of the body complained about;
 - (c) in the case of a complaint about an NHS foundation trust which falls within regulation 15(2), the views of the Independent Regulator;
 - (d) any investigation of the complaint, whether under Part II or otherwise, and any action taken as a result of such investigation; and
 - (e) any other relevant circumstances.
- (2) As soon as reasonably practicable the Healthcare Commission must notify the complainant as to whether it has decided—
- (a) to take no further action;
 - (b) to make recommendations to the body which is the subject of the complaint as to what action might be taken to resolve it;
 - (c) to investigate the complaint further in accordance with regulation 17, whether by establishing a panel to consider it or otherwise;
 - (d) to consider the subject matter of the complaint as part of or in conjunction with any other investigation or review which it is conducting or proposes to conduct in the exercise of its functions under the 2003 Act;
 - (e) to refer the complaint to a health regulatory body;
 - (f) in the case of a complaint about an NHS foundation trust which falls within regulation 15(2), to refer the complaint to the Independent Regulator; or
 - (g) to refer the complaint to the Health Service Commissioner in accordance with section 10 of the Health Service Commissioners Act 1993.
- (3) The notice of decision mentioned in paragraph (2)—
- (a) must be sent to any person who or body which is the subject of the complaint;
 - (b) may be sent to any other body which the Healthcare Commission considers has an interest in it;
 - (c) must include the Healthcare Commission's reasons for its decision; and
 - (d) in the case of a notification under paragraph (2)(a), must inform the complainant of his right to refer his complaint to the Health Service Commissioner.
- (4) For the purposes of its decision under this regulation, the Healthcare Commission may—
- (a) distinguish one part of a complaint from another and make different proposals in respect of those different parts; and
 - (b) take such advice as appears to it to be required.

Investigation by the Healthcare Commission

17.—(1) Where the Healthcare Commission proposes to investigate a complaint itself, it must, within 10 working days of the date on which it sent the notice mentioned in regulation 16(2), or where that is not possible, as soon as reasonably practicable, send to the complainant and any other person to whom the notice was sent its proposed terms of reference for its investigation.

(2) The complainant and any person or body to whom the terms of reference are sent as mentioned in paragraph (1) may comment in writing on the proposed terms of reference provided that they do so within 10 working days of the date on which they were sent.

(3) The Healthcare Commission may conduct its investigation in any manner which seems to it appropriate, may take such advice as appears to it to be required and, having regard in particular to the views of the complainant and any person who or body which is the subject of the complaint, may appoint a panel to hear and consider the complaint in accordance with regulation 18.

(4) The Healthcare Commission may request any person or body to produce such information and documents as it considers necessary to enable a complaint to be considered properly.

(5) A request under paragraph (4) must be in writing (which may be electronically), must specify what information is requested and state why it is relevant to the consideration of the complaint.

(6) The Healthcare Commission may not make a request under paragraph (4) for information which is confidential and relates to a living individual unless the individual to whom the information relates has consented, such consent may be either express or implied, to its disclosure and use for the purposes of the investigation of the complaint.

Panels

18.—(1) Subject to paragraph (2), the Healthcare Commission must prepare and keep up to date a list of people who, in its opinion, are suitable to be members of an independent lay panel to hear and consider complaints.

(2) The following persons are not eligible for membership of an independent lay panel—

- (a) a member or employee of an NHS body;
- (b) any person who is, or who has at any time been, a health care professional or an employee of a health care professional.

(3) Where the Healthcare Commission proposes to refer a complaint to a panel it must make arrangements for the complaint to be considered by a panel of three people selected from the list mentioned in paragraph (1), one of whom must be appointed to be the chairman.

(4) Subject to paragraphs (5) to (7), a panel may consider a complaint in any manner and adopt any procedure which appears to it to be appropriate to resolve the complaint, having regard to any representations to it which may be made by the complainant or by the person who is the subject of the complaint (in this regulation referred to as the participants).

(5) The panel must ensure that the participants are kept informed generally and in particular about—

- (a) the composition of the panel;
- (b) the date and time of any hearing; and
- (c) the names of any person whom the panel proposes to interview or from whom it proposes to take advice or evidence.

(6) A participant before a panel may be accompanied or represented by a friend or advocate but may not be represented by a legal representative acting as such.

(7) In the event of disagreement among members of the panel, the view of the majority shall prevail.

Report of investigation by the Healthcare Commission

19.—(1) Where the Healthcare Commission investigates a complaint it must, as soon as reasonably practicable, prepare a written report of its investigation which—

- (a) summarises the nature and substance of the complaint;
- (b) describes the investigation and summarises its conclusions including any findings of fact, the Healthcare Commission's opinion of those findings and its reasons for its opinion;
- (c) recommends what action should be taken and by whom to resolve the complaint; and
- (d) identifies what other action, if any, should be taken and by whom.

(2) The report may include suggestions which it considers would improve the services of an NHS body, an NHS foundation trust or a primary care provider, or which would otherwise be effective for the purpose of resolving the complaint.

(3) Subject to paragraph (4), the report must be sent to—

- (a) the complainant together with a letter explaining to him his right to take his complaint to the Health Service Commissioner;
- (b) the body which was the subject of the complaint and, in the case of a complaint arising out of services provided by an independent provider, the body which commissioned those services;
- (c) in the case of a complaint involving a primary care provider, to the relevant Primary Care Trust;
- (d) any relevant Strategic Health Authority; and
- (e) in the case of a complaint involving an NHS foundation trust to the Independent Regulator.

(4) The Healthcare Commission must adapt the report to ensure that confidential information from which the identity of a living individual can be ascertained is not disclosed without the express consent of the individual to whom it relates.

PART IV GENERAL

Publicity

20.—(1) Each NHS body and the Healthcare Commission must ensure that there is effective publicity for its complaints arrangements.

(2) Each NHS body must take all reasonable steps to ensure that the persons listed in paragraph (3) are informed of its arrangements, the name of its complaints manager and the address at which he can be contacted.

(3) The persons referred to in paragraph (2) are—

- (a) patients and their carers;
- (b) visitors to any hospital or other premises for the management of which the NHS body is responsible;
- (c) staff of the NHS body;
- (d) independent providers with whom arrangements have been made under section 16CC or section 23 of the 1977 Act;
- (e) any body with which it has made an NHS contract; and
- (f) its relevant patients' forum.

Monitoring

21.—(1) For the purpose of monitoring the arrangements under these Regulations each NHS body must prepare a report for each quarter of the year for consideration by its Board.

(2) The reports mentioned in paragraph (1) must—

- (a) specify the numbers of complaints received;
- (b) identify the subject matter of those complaints;
- (c) summarise how they were handled including the outcome of the investigations; and
- (d) identify any complaints where the recommendations of the Healthcare Commission were not acted upon, giving the reasons why not.

Annual reports

22. Each NHS body must prepare an annual report on its handling and consideration of complaints and send a copy of that report —

- (a) in the case of a Strategic Health Authority or Special Health Authority, to the Healthcare Commission;
- (b) in the case of an NHS trust, to its relevant Strategic Health Authority and the Healthcare Commission; and
- (c) in the case of a Primary Care Trust, to its relevant Strategic Health Authority and the Healthcare Commission.

PART V

TRANSITIONAL PROVISION AND REVOCATIONS

Transitional provision

23.—(1) In this regulation “former complaints provisions” means any of the directions in relation to complaints given under section 17 of the 1977 Act which are revoked by regulation 24.

(2) Subject to paragraphs (3) and (4), where before 30th July 2004, a complaint has been made in accordance with any former complaints provisions, it must be investigated, or in an appropriate case continue to be investigated, in accordance with those provisions.

(3) Except where paragraph (4) applies, where an investigation of a complaint has been conducted and completed by the complaints manager of an NHS body in accordance with any former complaints provisions, Part III of these Regulations (handling and consideration of complaints by the Healthcare Commission) shall apply.

(4) Where, in accordance with former complaints provisions—

- (a) an investigation of a complaint has been conducted and completed as mentioned in paragraph (3); and
- (b) the person who made the complaint has made a request to an NHS body for a review by an independent review panel,

the independent review panel must be established in accordance with the former complaints provisions, conduct its investigation and make a report in accordance with those provisions.

Revocations

24. The following directions made under section 17(1) of the 1977 Act^(a) are revoked—

- (a) The Directions to NHS, Health Authorities and Special Health Authorities for Special Hospitals on Hospital Complaints Procedures 1996;
- (b) The Miscellaneous Directions to Health Authorities for dealing with complaints 1996;
- (c) The Directions to Health Authorities on dealing with complaints about family health services practitioners and providers of personal medical services 1998;
- (d) The Directions to Primary Care Trusts on dealing with complaints about providers of personal dental services other than NHS trusts 1998;
- (e) The Directions to Primary Care Trusts on dealing with complaints 2002, made on 1 October 2002;
- (f) The Directions to Health Authorities on dealing with complaints about Family Health Services Practitioners and personal medical services (Amendment) Directions 2002;
- (g) The Directions to Health Authorities on dealing with complaints about providers of personal dental services other than NHS trusts (Amendment) Directions 2002; and
- (h) The Directions to Primary Care Trusts on complaints procedures for primary medical services 2004, made on 31 March 2004

Signed by authority of the Secretary of State for Health

9th July 2004

Rosie Winterton
Minister of State,
Department of Health

^(a) Copies of these Direction are available from the Department of Health, Room 5C 05, Quarry House, Quarry Hill, Leeds LS2 7UE.

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations make provision for complaints in the National Health Service. They require NHS bodies to establish and operate complaints procedures with a view to securing a speedy resolution of complaints at local level. Where such resolution is not achieved, the regulations provide for complaints to be considered by the Commission for Healthcare, Audit and Inspection (the Healthcare Commission) established under section 41 of the Health and Social Care (Community Health and Standards) Act 2003.

Regulation 3 imposes on NHS bodies an obligation to make arrangements for the handling and consideration of complaints. Regulation 4 requires the designation of a senior member of the NHS body to take responsibility for the complaints procedures and regulation 5 requires the appointment of a complaints manager. Regulation 6 is about the nature of complaints to NHS bodies and regulation 7 excludes certain types of complaint from the ambit of the Regulations. There then follows provision as to who may make a complaint (regulation 8), how a complaint should be made (regulation 9), what time limits apply (regulation 10), and how it is to be processed initially (regulation 11). Local level investigation and the response to the claimant are covered in regulations 12 and 13.

Part III of the Regulations is about handling and consideration of complaints by the Healthcare Commission. The Healthcare Commission's remit in relation to complaints, which is dealt with in regulation 14, extends to consideration of complaints made about primary care. By regulation 15 it also extends to complaints made about the provision of health care and other services to patients by NHS foundation trusts. Provision is made for how a complaint is to be made (regulations 14 and 15), the Healthcare Commission's decision on how to handle a complaint (regulation 16) and its investigation (regulation 17). Where the Healthcare Commission considers it appropriate, its investigation may involve an independent panel of three lay people. Regulation 18 is about the appointment and procedure of such panels. Regulation 19 is about the Healthcare Commission's report.

Part IV contains provision about publicity for complaints procedures (regulation 20), monitoring (regulation 21) and annual reports (regulation 22).

Transitional provision, consequential amendments and revocations are contained in Part V.

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