



THE NATIONAL HEALTH SERVICE ACT 2001

**THE NATIONAL HEALTH SERVICE (COMPLAINTS)
REGULATIONS 2004**

Laid before Tynwald *2004*

Coming into operation *1st July 2004*

In exercise of the powers conferred on the Department of Health and Social Security by section 38 of the National Health Service Act 2001¹, and of all other enabling powers, and after the consultations required by section 42(5) of that Act, the following Regulations are hereby made:—

1. Citation commencement and interpretation

(1) These Regulations may be cited as the National Health Service (Complaints) Regulations 2004, and shall come into operation on the 1st July 2004

(2) In these Regulations —

"the Act" means the National Health Service Act 2001;

"convenor" means a person appointed under regulation 21;

"complainant" means any person who makes or has made a complaint in accordance with regulation 9;

"complaints manager" means the person appointed under regulation 8;

"disciplinary proceedings" means any procedure for disciplining employees adopted by the Department;

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

"health regulatory body" means a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professionals Act 2002² (an Act of Parliament);

"Panel" means the Independent Review Panel established under section 2 of the Act;

¹ 2001 c.14

² 2002 c.17

“primary care provider” means a person described in regulation 3;

“primary care services” means services provided under Part 2 of the Act;

“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 under the Bank Holidays Act 1989³.

2. Arrangements about the handling and consideration of complaints

(1) The Department must make arrangements in accordance with these Regulations for the handling and consideration of complaints.

(2) Each primary care provider must make arrangements in accordance with these Regulations for the handling and consideration of complaints (in these Regulations referred to as a primary care complaints procedure).

(3) 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.

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

3. Primary Care Complaints

(1) For the purposes of these Regulations, a primary care provider means -

- (a) a general medical services contractor;
- (b) a dental practitioner who is providing general dental services;
- (c) an ophthalmic optician or an ophthalmic medical practitioner who provides general ophthalmic services; and
- (d) a general pharmaceutical services contractor

in accordance with arrangements made under Part 2 of the Act.

(2) A complaint to a primary care provider may be made about any matter connected with the provision of primary care services which is or was the responsibility of or in the control of -

- (a) the provider;
- (b) where the provider is a body corporate, any of its directors or former directors;
- (c) a partner or former partner of the provider;
- (d) an employee or former employee of the provider; or
- (e) a person engaged to provide services on behalf of the provider.

³ 1989 c.5

(3) A primary care complaints procedure may be such that it deals with complaints made in relation to

- (a) one or more primary care providers; or
- (b) the provision of primary care services from more than one set of premises.

4. Complaints in relation to independent providers

Where the Department 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.

5. Matters excluded from consideration under the arrangements

The following complaints are excluded from the scope of the arrangements required under these Regulations

- (a) a complaint made by a primary care provider which relates to the contract or arrangements under which it provides primary care services;
- (b) a complaint made by an employee of a primary care provider about any matter relating to his contract of employment;
- (c) a complaint made by an independent provider about any matter relating to arrangements made by the Department with that independent provider; and
- (d) a complaint which has been investigated by an Independent Review Panel.

6. General duty to co-operate

(1) The arrangements under these Regulations must be such as to ensure that a full and comprehensive response is given to a complainant and to that end that there is all necessary co-operation in the handling and consideration of complaints between primary care providers and the Department.

(2) The general duty to co-operate required by paragraph (1) includes in particular a duty to -

- (a) answer questions reasonably put by the body carrying out the investigation,
- (b) provide any information relating to the complaint which is reasonably requested by the Department, and
- (c) attending any meeting reasonably required to consider the complaint.

7. Responsibility for complaints arrangements

The Department and each primary care provider must designate a person 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.

8. Complaints manager

(1) The Department and each primary care provider must appoint 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;
- (b) to perform such other functions in relation to complaints as the Department may require; and
- (c) to co-operate with such other persons or bodies as may be necessary in order to investigate or resolve complaints.

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

(3) A complaints manager may be -

- (a) a person who is not an employee of the primary care provider; or
- (b) appointed as complaints manager for more than one body.

9. Persons who may make complaints

(1) A complaint may be made by-

- (a) a patient;
- (b) a former patient; or
- (c) any person who is affected by or likely to be affected by the action, omission or decision of the Department or primary care provider 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;
- (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.

(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 the Department, the representative must be a person authorised by the Department.

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

10. Making a complaint

(1) Where a person wishes to make a complaint under these Regulations, he may make the complaint to the complaints manager or any member of the staff of the Department or primary care provider 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 a complaint is made on the date on which it was received by the complaints manager or where it was made orally, on the date on which it was recorded by him.

11. Complaints which need not be considered

A complaint need not be considered under these Regulations where

- (a) the subject of a complaint is such that it can be quickly and effectively resolved by a member of the staff of the body to which the complaint was made or by the complaints manager, and
- (b) the complainant agrees that no further action is required.

12. Time limit for making a complaint

- (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.

13. Acknowledgement and record of complaint

- (1) Except in a case to which regulation 11 applies, 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 10(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 -
 - (a) any person identified in it as the subject of the complaint unless in the opinion of the complaints manager notification at that time to that person would prejudice the consideration of the complaint; and
 - (b) the complaints manager of any other body to which the complaint relates.
- (4) In any case where a person who is subject to a complaint is not notified as mentioned in paragraph (3)(a), he must be notified as soon as reasonably practicable.

14. Initial handling of certain complaints

- (1) In any case where it appears to the complaints manager that a complaint is or may be a complaint described in regulation 15(1), he must, as soon as reasonably practicable
 - (a) notify the other body involved and consider with its complaints manager which of them should take the lead in the handling and considering the complaint (in this regulation referred to as the lead body); and

(b) notify the complainant of their decision.

(2) The complaints manager of the Department or primary care provider which is the lead body must -

- (a) ensure that any part of the complaint relating to the exercise of its functions is considered in accordance with these Regulations
- (b) ensure that the complainant is kept informed about the progress of the investigation; and
- (c) ensure that the response required under regulation 18 so far as practicable includes a response on any matter which was within the responsibility or control of any other primary care provider.

(3) The complaints manager of the Department or primary care provider which is not the lead body must -

- (a) ensure that any part of the complaint relating to the exercise of its functions is considered in accordance with these Regulations;
- (b) advise the complaints manager of the lead body of any resolution of the complaint or outcome of any investigation under regulation 17.
- (c) contribute to and approve any response sent to the complainant by the lead body.

15. Matters subject to concurrent investigation

(1) Where a complaint relates to any matter -

- (a) about which the complainant has stated in writing that he intends to take legal proceedings;
- (b) about which the Department or primary care provider 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) which the Department or primary care provider has referred to the police or to a health regulatory body; or
- (d) which is the subject of any statutory inquiry or other investigation,

the Department or primary care provider must consider, in consultation with the complainant and any other person or body which it considers it appropriate to consult, how the complaint should be handled.

(2) The complaints manager may investigate the complaint in accordance with regulation 17, notwithstanding the concurrent investigation, in any case where the Department or primary care provider considers that to do so would not compromise or prejudice the concurrent investigation.

(3) The investigation of a complaint which is subject to a concurrent investigation may be discontinued if at any time it appears to the Department or primary care provider that to continue would compromise or prejudice the concurrent investigation.

(4) Where the complaints manager either does not investigate or discontinues investigation of a complaint which is subject to a concurrent investigation -

- (a) he may at any time start or, as the case may be, resume an investigation; and
- (b) he must start, or as the case may be, resume an investigation in any case where a concurrent investigation is discontinued or completed and the complainant requests that an investigation should take place.

(5) Where he conducts an investigation into a complaint which is also subject to another investigation mentioned in paragraph (1), the complaints manager must take all reasonable steps to ensure that the complainant is kept informed of the progress of both investigations and that the response under regulation 17 is as comprehensive as possible.

(6) References in this regulation to a “concurrent investigation” or “investigation” include any proceedings, referral, inquiry or investigation described in paragraph (1).

16. Referral to the Independent Review Panel

(1) Subject to paragraph (2), in any case where it appears appropriate to the Department or a primary care provider to do so and at any stage of the consideration of a complaint under these Regulations, the complaints manager may refer a complaint to one of a convenor for consideration under regulations 19 to 22.

(2) A referral under paragraph (1) may be made only with the consent of the complainant and the agreement of the Panel.

17. Investigation

(1) Subject to regulations 14 and 15 and except where he has referred a complaint to another person or body in accordance with regulation 16, 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) A complaints manager may request any person or body to produce such information and documents as he considers necessary to enable a complaint to be considered properly.

(3) A request under paragraph (2) 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.

(4) The complaints manager may not make a request under paragraph (2) for information which is confidential and relates to a living individual unless either -

- (a) the individual to whom the information relates has consented to its disclosure and use for the purposes of the investigation of the complaint; or
 - (b) it can be supplied in a form from which the identity of the individual cannot be ascertained.
- (5) The complaints manager may -
- (a) invite the complainant and any other person who he considers would be in a position to assist with the resolution of the complaint to be interviewed;
 - (b) 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
 - (c) take such advice as appears to him to be required.
- (6) The complaints manager must take such steps as are reasonably practicable to keep the complainant informed about the progress of the investigation.

18. Response

- (1) The complaints manager must prepare a written response to the complaint which -
- (a) summarises the nature and substance of the complaint;
 - (b) describes the investigation under regulation 17 and summarises the conclusions;
 - (c) explains what action will be or has been taken to resolve the complaint;
 - (d) where appropriate, contains an apology to the complainant; and
 - (e) identifies what action, if any, will be taken in the light of the complaint.
- (2) The response must be signed by or on behalf of the designated person mentioned in regulation 7.
- (3) Subject to paragraph (4), the response must be sent to the complainant as soon as possible and in any event within 25 working days beginning on the date on which the complaint was made.
- (4) If, in the case of –
- (a) a complaint described in regulation 15(1); or
 - (b) any other complaint where the complainant has agreed to a later response,

it is not possible for the response to be sent within 25 working days it must be sent as soon as reasonably practicable.

- (5) The response must notify the complainant of his right to refer the complaint to Panel in accordance with regulation 19.

- (6) Copies of the response mentioned in paragraph (1) must be sent to -
 - (a) any person who was the subject of the complaint;
 - (b) any other person to whom the complaint was sent under regulation 9(3).

19. Complaints to the Convenor

- (1) In any case where -
 - (a) a complainant is not satisfied with the result of an investigation by the Department or primary care provider under regulation 17,
 - (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 12,

a complainant may request that one of the Convenors should consider the complaint in accordance with regulations 19 to 22.

(2) A request under paragraph (1) must be made either on a form supplied for the purpose or in writing (including electronically) and may be made

- (a) to one of the Convenors; or
- (b) to the Department or as the case may be primary care body which was the subject of the complaint.

(3) Where a request is made to the Department or primary care provider as mentioned in paragraph (2)(b), the request must be forwarded immediately to one of the Convenors and in all cases a copy of the response mentioned in regulation 18 and all other information or documents relating to the Department or primary care provider's handling and consideration of the complaint must be forwarded to the Convenor as soon as possible.

(4) A request under paragraph (1) must be made within 2 months of, or as soon as reasonably practicable after, the date on which the response to the investigation under regulation 17 was sent to the complainant.

(5) The Convenor must send a written acknowledgement of the complaint to the complainant within 2 working days of the date on which it was received or as soon as reasonably practicable.

20. Decision on handling of complaint

(1) On receipt of the complaint the Convenor 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) any investigation of the complaint under regulations 7 to 18 and any action taken as a result of such investigation; and
- (d) any other relevant circumstances.

(2) Within 10 working days of the date on which the complaint was received the Convenor must notify the complainant as to whether he proposes -

- (a) to take no further action;
- (b) to refer the complaint back to the Department or primary care provider which is the subject of the complaint with recommendations as to what action might be taken to resolve it;
- (c) to investigate the complaint further in accordance with regulation 21;
- (d) with the agreement of the complainant, to refer the complaint to a panel in accordance with regulation 22; or
- (e) to refer the complaint to a health regulatory body,

(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 Convenor considers has an interest in it; and
- (c) must include the Convenor's reasons for its decision.

(4) For the purposes of its decision under this regulation, the Convenor 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.

21. The Convenor

(1) Subject to paragraph 2, the Department shall appoint three lay people to be Convenors to carry out the functions of convenor under these Regulations

(2) The following persons are not eligible to be appointed a Convenor -

- (a) a member or employee of the Department;
- (b) any person who is, or who is an employee of, a health care professional.

22. Investigation by one of the Convenors

(1) Where the Convenor proposes to investigate a complaint himself, he must as soon as reasonably practicable and in any event within 10 working days of the date on which it sent the notice mentioned in regulation 20(2) 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 7 working days of the date on which they were sent.

(3) The Convenor may conduct his investigation in any manner which seems to it appropriate, may take such advice as appears to it to be required and may appoint a panel to conduct the investigation in accordance with regulation 22.

(4) Paragraphs (2) to (4) of regulation 17 (information) apply to an investigation by the Convenor as if the reference in paragraph (2) to the complaints manager were a reference to the Convenor.

23. Panels

(1) Subject to paragraph (2), the Department 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

- (c) a member or employee of the Department;
- (d) any person who is, or who is an employee of, a health care professional.

(3) Where either-

- (a) the Convenor proposes to refer a complaint to a panel as mentioned in regulation 20(2)(d); or
- (b) a complainant requests a panel,

the Convenor 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 by the Convenor to be the Chairman.

(4) Subject to paragraphs (5) to (8), a panel may consider a complaint in any manner and adopt such 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 participants must be given the opportunity of being heard in person.

(6) 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 who the panel proposes to interview or from whom it proposes to take advice or evidence.

(7) 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.

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

24. Publicity

(1) The Department, each primary care provider and the Convenor must ensure that there is effective publicity for its complaints arrangements in accordance with paragraphs (2) to (4).

(2) The Department 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; and
- (b) visitors to any hospital or other premises for the management of which the Department is responsible.

(4) The Department must take all reasonable steps to ensure that patients, their carers and any visitors to any premises for which they are responsible are informed of the provider's complaints procedures.

25. Training

The Department and each primary care provider must ensure that its staff are informed about and appropriately trained in the operation of the complaints arrangements.

26. Monitoring

(1) For the purpose of monitoring the arrangements under these Regulations each primary care provider must prepare an annual report to the Department.

(2) The reports mentioned in paragraph (1) must specify the numbers of complaints received, identify the subject matter of those complaints and summarise how they were handled including the outcome of the investigations.

27. Annual report

The Department must prepare an annual report on its handling and consideration of complaints and place the report before Tynwald.

MADE

2004

Minister for Health and Social Security.

EXPLANATORY NOTE
(This note is not part of the Order)

These Regulations make provision for complaints in the National Health Service. They require the Department and primary care providers to establish and operate complaints procedures with a view to securing a reasonably speedy resolution of complaints at local level. Where such resolution is not achieved, the regulations provide for complaints to be considered by the Independent Complaints Panel.