

Statutory Document No. 2004/0216

*National Health Service Act 2001*

# NATIONAL HEALTH SERVICE (COMPLAINTS) REGULATIONS 2004<sup>1</sup>

*Laid before Tynwald:* 14 December 2004  
*Coming into Operation:* 1 January 2005

In exercise of the powers conferred on the Department of Health and Social Security by section 38 of the National Health Service Act 2001<sup>1</sup> 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 January 2005.
- (2) In these Regulations —
  - “**the Act**” means the National Health Service Act 2001;
  - “**complainant**” means any person who makes or has made a complaint in accordance with regulation 6;
  - “**complaints manager**” means the person appointed under regulation 3;
  - “**Department**” means the Department of Health and Social Security;
  - “**disciplinary proceedings**” means any procedure for disciplining employees adopted by the Department or by the primary care provider;
  - “**general medical services contractor**” means a person who has entered into a general medical services contract with the Department under section 31 of the Act;
  - “**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 2002<sup>2</sup> (an Act of Parliament);

<sup>1</sup> 2001 c.14

<sup>2</sup> 2002 c.17

“**independent provider**” means a person or body, including a voluntary organisation which is providing services under arrangements (other than with a primary care provider) made with the Department in accordance with the Act;

“**Independent Review Body**” means the body established by the Department under section 2 of the Act;

“**patient**” in regulation 5 means a person who is receiving or has received services from the Department, a primary care provider or an independent provider;

“**primary care provider**” has the meaning given in paragraph (3);

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

“**staff**” means any person who is employed by, or engaged to provide services to the Department, a primary care provider or an independent provider;

“**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 1989<sup>3</sup>.

- (3) A primary care provider means —
- (a) a general medical services contractor;
  - (b) a dental practitioner who provides general dental services in accordance with arrangements made under Part 2 of the Act;
  - (c) a person who provides general pharmaceutical services in accordance with arrangements made under Part 2 of the Act; and
  - (d) an ophthalmic optician or ophthalmic medical practitioners who provides general ophthalmic services in accordance with arrangements made under Part 2 of the Act.

## 2 Arrangements about the handling and consideration of complaints

- (1) The Department and primary care providers 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 the Department or primary care provider makes arrangements for the provision of services with an independent provider, it must ensure

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<sup>3</sup> 1989 c.5

that the independent provider has in place arrangements for the handling and consideration of complaints about any matter connected to its provision of services as if these regulations applied to it.

### **3 Complaints manager**

- (1) The Department and each primary care provider 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 these regulations; and
  - (b) to perform such other functions in relation to complaints as the Department or primary care provider may require.
- (2) The functions of the complaints manager may be performed by him or by any person authorised by the Department or primary care provider to act on his behalf.

### **4 Complaints to the Department and primary care providers**

- (1) Subject to paragraph (2), a complaint to the Department or primary care provider may be about any matter reasonably connected with the exercise of its functions under the Act.
- (2) 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 the Department or primary care provider about a 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;
  - (d) a complaint which has been investigated by the Independent Review Body;
  - (e) a complaint arising out of the Department's or primary care provider's alleged failure to comply with a data subject request under the Data Protection Act 2002<sup>4</sup>;
  - (f) a complaint about which the complainant has stated in writing that he intends to take legal proceedings; and
  - (g) a complaint about which the Department or primary care provider is taking or is proposed to take disciplinary proceedings in relation

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<sup>4</sup> 2002 c.2

to the substance of the complaint against a person who is the subject of the complaint.

## **5 Persons who may make complaints**

- (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 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; 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.
- (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.

## **6 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 where a complaint is made in writing it is to be treated as being made on the date on which it was received by the complaints manager or as the case may be, other member of the staff of the Department or primary care provider.

## **7 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.

## **8 Acknowledgement and record of complaint**

- (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 6(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.

## **9 Investigation**

- (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 Department 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.

## **10 Response**

- (1) The complaints manager must prepare a written response to the complainant which summarises the nature and substance of the complaint, describes the investigation under regulation 9 and summarises its conclusions.
- (2) Subject to paragraph (3), 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 is reasonably practicable.
- (3) The response must notify the complainant of his right to refer the complaint to the Independent Review Body in accordance with regulation 11.
- (4) Copies of the response mentioned in paragraph (1) must be sent to any other person to whom the complaint was sent under regulation 8(3).

## **11 General complaints remit of the Independent Review Body**

- (1) In any case where —
  - (a) a complainant is not satisfied with the result of an investigation —
    - (i) by the Department or primary care provider under regulation 9, or
    - (ii) by an independent provider, with whom the Department has made arrangements as mentioned in regulation 2(4), 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 7;

the complainant may request the Independent Review Body to consider the complaint in accordance with these Regulations.

- (2) In any case where a person has made a complaint to a primary care provider or independent provider and is not satisfied with the outcome of an investigation of his complaint, he, or a person who acted as his

representative in accordance with those procedures, may request the Independent Review Body to consider the complaint in accordance with these regulations.

- (3) A request under paragraphs (1) or (2) may be made either orally or in writing (including electronically) and must be made within 28 days of, or where that is not possible, as soon as reasonably practicable after, the date on which the response mentioned in regulation 10, or, as the case may be, under the complaints arrangements of the primary care provider, was sent to the complainant.

## 12 Decision on handling of complaint

- (1) On receipt of the complaint the Independent Review Body 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 Department, primary care provider or independent provider (in this regulation referred to as “the body”) complained about;
  - (c) any investigation of the complaint, and any action taken as a result of such investigation; and
  - (d) any other relevant circumstances.
- (2) As soon as reasonably practicable the Independent Review Body 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 14, whether by establishing a panel to consider it or otherwise; or
  - (d) 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 or body which is the subject of the complaint;
  - (b) may be sent to any other body which the Independent Review Body considers has an interest in it; and
  - (c) must include the Independent Review Body’s reasons for its decision.
- (4) For the purposes of its decision under this regulation, the Independent Review Body 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.

### **13 Investigation by the Independent Review Body**

- (1) Where the Independent Review Body proposes to investigate a complaint itself, it must, within 10 working days of the date on which it sent the notice mentioned in regulation 12(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 Independent Review Body 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 14.
- (4) The Independent Review Body 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 Independent Review Body 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.

### **14 Panels**

- (1) Where the Independent Review Body proposes to refer a complaint to a panel it must make arrangements for the complaint to be considered by a panel of three members of the Independent Review Body, one of whom must be appointed to be the chairman.
- (2) 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).

- (3) 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.
- (4) A participant before a panel may be accompanied or represented by a friend but may not be represented by a legal representative acting as such.
- (5) In the event of disagreement among members of the panel, the view of the majority shall prevail.

## **15 Report of investigation by a panel**

- (1) Where a panel 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 panel'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 the Department, primary care provider or independent 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;
  - (b) the body which was the subject of the complaint; and
  - (c) to the Department.
- (4) The panel 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.

## **16 Publicity**

- (1) The Department, each primary care provider and the Independent Review Body must ensure that there is effective publicity for its complaints arrangements.
- (2) The Department, primary care providers and independent providers 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 or a primary care provider is responsible; and
  - (c) staff employed by the Department, primary care providers or independent providers.

## **17 Monitoring**

- (1) For the purpose of monitoring the arrangements under these Regulations each primary care provider and independent provider must prepare an annual report to the Department.
- (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;
  - (d) identify any complaints where recommendations of the Independent Review Body were not acted upon, giving the reasons why not.

## **18 Annual report**

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

**MADE 1 NOVEMBER 2004**

## ENDNOTES

### Table of Endnote References

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<sup>1</sup> The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.