



## NATIONAL HEALTH SERVICE (COMPLAINTS) REGULATIONS 2022

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Statutory Document No. 2022/0221



*National Health Service Act 2001*

## NATIONAL HEALTH SERVICE (COMPLAINTS) REGULATIONS 2022

*Approved by Tynwald:*

*Coming into operation in accordance with regulation 2*

The Department of Health and Social Care makes the following Regulations under section 38 of the National Health Service Act 2001<sup>1</sup> after satisfying the requirements of section 42(5) of the National Health Service Act 2001<sup>2</sup>.

### PART 1 – INTRODUCTION

#### 1 Title

These Regulations are the National Health Service (Complaints) Regulations 2022.

#### 2 Commencement

If approved by Tynwald, these Regulations come into operation on 31 October 2022.<sup>3</sup>

#### 3 Interpretation

(1) In these Regulations –

“**the Act**” means the National Health Service Act 2001;

“**the 2004 Complaints Regulations**” means the National Health Service (Complaints) Regulations 2004<sup>4</sup>;

<sup>1</sup> Section 38 of the National Health Service Act 2001 was substituted by SD 2022/0211.

<sup>2</sup> Under section 42(5) of the National Health Service Act 2001 before making any regulations the Department shall consult the body established under section 2(1) of the National Health Service Act 2001 and any profession appearing to the Department to be affected by the regulations.

<sup>3</sup> Tynwald approval is required under section 42(1) of the National Health Service Act 2001.

<sup>4</sup> SD 216/04. SD 216/04 was amended by SD 2021/0067.

“**the 2004 Independent Review Body Regulations**” means the National Health Service (Independent Review Body) Regulations 2004<sup>5</sup>;

“**applied GDPR**” and “**GDPR**” have the meanings given in the Data Protection (Application of GDPR) Order 2018<sup>6</sup>;

“**chairperson**” means the chairperson of the Health and Social Care Ombudsman Body and includes the vice-chairperson appointed under regulation 5 of the Health and Social Care Ombudsman Body (Constitution, etc.) Regulations 2022<sup>7</sup>;

“**child**” means an individual who has not attained the age of 18;

“**complainant**” means any person who makes or has made a complaint in accordance with Part 2 or Part 3;

“**complaint**” means —

- (a) in Part 2, a complaint made to a service provider under Part 2; and
- (b) in Part 3, a complaint made to the Health and Social Care Ombudsman Body under Part 3;

“**complaints manager**” means the person designated under regulation 5(1)(b);

“**data protection legislation**” has the meaning given in regulation 5(1) of the GDPR and LED Implementing Regulations 2018<sup>8</sup> as they have effect from time to time;

“**Health and Social Care Ombudsman Body**” means the body established under section 26A of the Social Services Act 2011;

“**health or social care regulatory body**” means a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professionals Act 2002<sup>9</sup> (of Parliament) and any other body performing similar functions under any other UK legislation as it operates from time to time;

“**health services**” means the services referred to in the Act;

“**the mandate**” has the meaning given in section 14 of the Manx Care Act 2021;

“**Manx Care**” means the statutory board established under the Manx Care Act 2021;

“**Manx Care annual report**” has the meaning given in regulation 14(2)(a);

“**relevant complaints procedure**” means —

- (a) any arrangements for the handling and consideration of complaints under —

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<sup>5</sup> SD 679/04. SD 679/04 was amended by SD 2021/0066.

<sup>6</sup> SD2018/0143.

<sup>7</sup> SD 2022/0214.

<sup>8</sup> SD 2018/0145.

<sup>9</sup> 2002 c.17.

- (i) paragraph 30 of Part 4 of Schedule 1 to the National Health Service (Pharmaceutical Services) Regulations 2005<sup>10</sup> (terms of service of pharmacists);
  - (ii) paragraph 9 of Schedule 1 to the National Health Service (General Ophthalmic Services) Regulations 2004<sup>11</sup>;
  - (iii) paragraph 2 of Schedule 2 to the Manx Care Act 2021 of a person with whom Manx Care has entered into an agreement under section 17 of the Manx Care Act 2021;
- (b) any arrangements for the investigation of a complaint relating to the provision of general dental services by a dentist to a patient;

**“responsible person”** means the person designated under regulation 5(1)(a);

**“secretary”** means an employee of the Public Services Commission whose duties include the provision of secretarial services to the Health and Social Care Ombudsman Body;

**“staff”** in relation to a service provider, means any person who is employed by, or engaged to provide services to, the service provider and, in relation to Manx Care, includes any person who is a member of Manx Care’s staff within the meaning of the Manx Care Act 2021.

- (2) A body is not a service provider in relation to a complaint insofar as that body must make arrangements for the handling and consideration of that complaint in accordance with any of the following UK legislation as in operation from time to time –
- (a) the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009<sup>12</sup>; or
  - (b) any other UK legislation which has an analogous effect to that of these Regulations.

## PART 2 – HANDLING, CONSIDERATION AND DISPOSAL OF COMPLAINTS BY SERVICE PROVIDERS

### 4 Arrangements for the handling, consideration and disposal of complaints

- (1) Each service provider must make arrangements (“arrangements for dealing with complaints”) for the handling, consideration and disposal of complaints.
- (2) The arrangements for dealing with complaints must be accessible and such as to ensure that –

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<sup>10</sup> SD727/05.

<sup>11</sup> SD18/04.

<sup>12</sup> SI 2009/309.

- (a) complaints are welcomed in a positive way;
  - (b) complaints are dealt with speedily and efficiently;
  - (c) complaints are investigated thoroughly and fairly;
  - (d) complainants are treated with respect and courtesy;
  - (e) complainants receive a timely and appropriate response and are given fair and accountable responses;
  - (f) complainants are told the outcome of the investigation of their complaint;
  - (g) action is taken, if necessary, in light of the outcome of the complaint; and
  - (h) a just and learning culture is promoted.
- (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.

## 5 Responsibility for complaints arrangements

- (1) Each service provider must designate —
- (a) a person, in these Regulations referred to as a responsible person, to be responsible for ensuring compliance with the arrangements made under this Part, and in particular ensuring that action is taken if necessary, and learning takes place, in the light of the outcome of a complaint; and
  - (b) a person, in these Regulations referred to as a complaints manager, to be responsible for managing the procedures for handling, considering and disposing of complaints in accordance with the arrangements made under this Part.
- (2) The functions of the responsible person may be performed by any person authorised by the responsible person to act on his or her behalf.
- (3) The functions of the complaints manager may be performed by any person authorised by the responsible person to act on behalf of the complaints manager.
- (4) The responsible person is to be —
- (a) in the case of the Department, the chief executive officer of the Department;
  - (b) in the case of Manx Care, the chief executive officer of Manx Care;
  - (c) in the case of any other service provider, the chief executive officer of the service provider or, if none —
    - (i) the person who is the sole proprietor of the service provider;
    - (ii) where the service provider is a partnership, a partner; or

- (iii) in any other case, a director of the service provider, or a person who is responsible for managing the service provider.
- (5) The complaints manager may be—
- (a) a person who is not an employee of the service provider; or
  - (b) a person who has been designated as a complaints manager by another service provider in respect of services provided by that other service provider.
- (6) The service provider must ensure that the complaints manager —
- (a) is suitably qualified and experienced;
  - (b) is provided with sufficient resources; and
  - (c) has sufficient authority,
- to perform the functions of the complaints manager effectively.

## **6 Persons who may make complaints**

- (1) A complaint may be made by —
- (a) a person who is receiving or has received health services from a service provider; or
  - (b) any person who is affected, or likely to be affected, by any act, omission or decision of a service provider which provides health services.
- (2) A complaint may be made by a person (in this regulation referred to as a representative) acting on behalf of a person mentioned in paragraph (1) who—
- (a) has died;
  - (b) is a child;
  - (c) is unable to make the complaint themselves because of physical or mental incapacity; or
  - (d) has requested the representative to act on their behalf.
- (3) Where a representative makes a complaint on behalf of a child, the service provider to which the complaint is made—
- (a) must not consider the complaint unless it is satisfied that there are reasonable grounds for the complaint being made by a representative instead of the child; and
  - (b) if it is not so satisfied, must notify the representative in writing, and state the reason for its decision.
- (4) This paragraph applies where—
- (a) a representative makes a complaint on behalf of—
    - (i) a child;

- (ii) a person who has died; or
    - (iii) a person who is unable to make the complaint themselves because of mental incapacity; and
  - (b) the service provider to which the complaint is made is satisfied that the representative is not conducting the complaint in the best interests of the person on whose behalf the complaint is made.
- (5) Where paragraph (4) applies—
- (a) the complaint must not be considered or further considered under these Regulations; and
  - (b) the service provider must notify the representative in writing, and state the reason for its decision.
- (6) In this Part any reference to a complainant includes a reference to their representative within the meaning of this regulation.
- (7) In considering whether the representative is conducting the complaint in a person's best interest under paragraph (4), the service provider must consider, so far as is reasonably ascertainable, whether the representative is acting in a way that is consistent with the person's beliefs, values, wishes and feelings whether expressed orally, in writing or by behaviour in the past or present.

## **7 Complaints which may be made**

A complaint may be made to a service provider about any matter reasonably connected with the exercise of the service provider's functions in respect of health services.

## **8 Complaints not required to be dealt with**

- (1) Subject to paragraph (2), the following complaints are not required to be dealt with in accordance with these Regulations—
- (a) a complaint made by a service provider which relates to the contract or arrangements under which it provides services;
  - (b) a complaint made by an employee of a service provider about a matter relating to that employment;
  - (c) a complaint which—
    - (i) is made orally; and
    - (ii) is resolved to the complainant's satisfaction not later than the end of the third working day after the day on which the complaint was made;
  - (d) a complaint the subject matter of which has previously been disposed of under —
    - (i) these Regulations;



- (ii) the 2004 Complaints Regulations (including under arrangements for the handling and consideration of complaints put in place by an independent provider under regulation 2(4) of the 2004 Complaints Regulations); or
    - (iii) a relevant complaints procedure;
  - (e) a complaint arising out of the service provider's alleged failure to comply with a data subject request under the applied GDPR;
  - (f) a complaint arising out of the alleged failure by a service provider to comply with a request for information under the Freedom of Information Act 2015; and
  - (g) any complaint dealt with under any other enactment.
- (2) Where a complaints manager decides that a complaint is a complaint specified in paragraph (1) except where the complaint is a complaint specified in paragraph (1)(c), the service provider must as soon as reasonably practicable notify the complainant in writing of its decision and the reason for the decision.
- (3) Where a complaint specified in paragraph (1) is part of, or is connected with, another complaint which is not so specified, nothing in this regulation prevents that other complaint being handled in accordance with this Part.

## **9 Time limit for making a complaint**

- (1) A complaint must be made not later than 12 months after —
- (a) the date on which the matter which is the subject of the complaint occurred; or
  - (b) if later, the date on which the matter which is the subject of the complaint came to the notice of the complainant.
- (2) The time limit in paragraph (1) shall not apply if the complaints manager is satisfied that —
- (a) the complainant had good reasons for not making the complaint within that time limit; and
  - (b) notwithstanding the delay, it is still possible to investigate the complaint effectively and fairly.
- (3) Subject to paragraph (2), where a complaints manager decides that a complaint does not comply with the provisions specified in paragraph (1) —
- (a) the service provider is not required to consider the complaint, or consider it further, under these Regulations; and
  - (b) the service provider must as soon as reasonably practicable notify the complainant in writing of its decision and the reason for the decision.

## 10 Procedure before investigation

- (1) A complaint may be made orally or in writing.
- (2) A complainant may make the complaint to the complaints manager or any member of the staff of the service provider which is the subject of the complaint, and —
  - (a) where it is made orally the complaints manager must make a written record of the complaint; or
  - (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 this Part 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, another member of the staff of the service provider.
- (4) The service provider must acknowledge receipt of a complaint ('acknowledgment') not later than 5 working days after the day on which the complaint was received.
- (5) At the time it acknowledges the complaint, the service provider must invite the complainant to attend a meeting to discuss the complaint.
- (6) The acknowledgement must be —
  - (a) in writing; or
  - (b) in such way as the complainant has requested or consented to.
- (7) Where a complaint is made orally —
  - (a) the acknowledgement must be accompanied by the written record mentioned in paragraph (2)(a) with an invitation to the complainant to sign and return the written record; or
  - (b) at the request, or with the consent, of the complainant, the information contained in the written record may be communicated using another form of communication.
- (8) If the complaint is not resolved at the time of the acknowledgement, the acknowledgement must—
  - (a) include a summary of the complaint;
  - (b) include details of the arrangements for dealing with complaints made by the service provider;
  - (c) inform the complainant how long the complainant can expect to wait before receiving a further response from the service provider about the complaint;
  - (d) give the complainant information as to how the complainant can contact a member of staff acting on behalf of the service provider in relation to the handling, consideration and disposal of the complaint;

- (e) be accompanied by, or give the complainant, information as to how the complainant can access any other relevant guidance in relation to making a complaint; and
- (f) if appropriate, require the complainant to produce further information or documents to the complaints manager to enable the complaint to be properly considered.

## **11 Investigation, response and record-keeping**

- (1) The complaints manager must —
  - (a) arrange for the investigation of the complaint in a manner appropriate to resolve it speedily and efficiently;
  - (b) unless a response under paragraph (3) has been sent within 20 working days of the complaint being recorded, inform the complainant of the progress of the investigation and keep the complainant so informed on a regular basis thereafter.
- (2) As part of the investigation, the complaints manager must offer the complainant an opportunity to meet with a member of staff of the service provider who is familiar with the complaint and is qualified to answer questions about the subject matter of the complaint.
- (3) The complaints manager must prepare a written response on behalf of the service provider to the complainant, signed by the responsible person, which —
  - (a) summarises the nature and substance of the complaint;
  - (b) confirms whether the complaint in full or in part is upheld;
  - (c) describes the investigation under paragraph (1)(a);
  - (d) summarises —
    - (i) the conclusions reached in relation to the complaint;
    - (ii) any action taken or to be taken as a result of the complaint and a reasonable timescale for the completion of any action to be taken as a result of the complaint; and
  - (e) includes an apology, if appropriate.
- (4) The response must be sent to the complainant —
  - (a) before the end of the period of 20 working days beginning on the day on which the complaint was made; or
  - (b) if the investigation is not completed before the end of that period, as soon as is reasonably practicable after the investigation is completed and, in any case not later than the end of the period of 6 months beginning on the day on which the complaint was made.
- (5) If the service provider does not send the complainant a response within the time limit in paragraph (4)(a), the service provider must notify the

complainant in writing and explain the reasons for the delay and when the complainant can expect to receive the response.

- (6) A response under paragraph (3) and a notification under paragraph (5) must –
- (a) inform the complainant of the right to refer the complaint to the Health and Social Care Ombudsman Body; and
  - (b) provide the contact details for that body.
- (7) A response under paragraph (3) must also –
- (a) contain an offer by the service provider to supply the complainant with details of any services or support which it considers may provide assistance to the complainant; and
  - (b) contain an invitation for the complainant to meet the service provider to discuss the response.
- (8) A service provider must keep any information relating to a complaint for a period of 10 years beginning on the day on which the response is sent to the complainant.

## **12 Learning from complaints**

A service provider must –

- (a) ensure that any remedial action is taken promptly (including, where appropriate, correcting any failures or weaknesses in its systems and procedures and carrying out training of its staff);
- (b) have systems to record, analyse and report on the learning from complaints;
- (c) use the learning from complaints to prevent the same mistakes happening again or to improve services, as appropriate;
- (d) put in place appropriate mechanisms for complainants to share feedback about their experience of the handling, consideration and disposal of complaints by the service provider;
- (e) where a complaint indicates that the service provider, or any member of the staff of the service provider, has not complied with any relevant provision of a code of conduct issued by a health or social care regulatory body or with any other relevant professional requirement, the service provider must consider referring the complaint to that body and, if appropriate, do so; and
- (f) undertake a review of complaints every 3 months to establish any links with any reported and unreported incident within the meaning of the Manx Care (Duty of Candour Procedure) Regulations 2021<sup>13</sup>.

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<sup>13</sup> SD 2021/0069.

### 13 Publicity and guidance

- (1) A service provider must make information available to the public on —
  - (a) how a complaint may be made to it;
  - (b) its arrangements for dealing with complaints; and
  - (c) how further information about those arrangements may be obtained.
- (2) The Department must provide, both face-to-face and in writing, advice, sign-posting to relevant support services and guidance to people wishing to make a complaint.
- (3) Manx Care must establish and operate an advice and liaison service to provide a person dissatisfied with a service provided by, or on behalf of, Manx Care with—
  - (a) assistance to resolve an issue whose subject matter is one in respect of which a complaint could be made;
  - (b) assistance to enable them to understand the procedure in relation to making a complaint and the arrangements for dealing with complaints; and
  - (c) advice on where they may obtain independent assistance in making a complaint.

### 14 Monitoring

- (1) Service providers to whom this Part applies must monitor their operation of the arrangements for dealing with complaints under this Part.
- (2) For the purpose of reporting on the monitoring of arrangements for dealing with complaints under this Part —
  - (a) Manx Care must prepare and give the Department an annual report (a “Manx Care annual report”) for the Department; and
  - (b) a relevant service provider must prepare and give Manx Care an annual report (a “relevant service provider annual report”) for Manx Care.
- (3) A Manx Care annual report must —
  - (a) specify the numbers of complaints received in relation to the services provided —
    - (i) by Manx Care; and
    - (ii) on Manx Care’s behalf, by all relevant service providers;
  - (b) identify the subject matter of those complaints;
  - (c) identify the category of service provided under the Act, the Manx Care Act 2021 or the mandate into which the subject matter of those complaints falls;

- (d) summarise how complaints were handled, including the outcome of the investigations into those complaints;
  - (e) include a statement outlining changes or improvements to services or procedures as a result of consideration of complaints;
  - (f) include a statement on the training provided to persons in relation to the handling of complaints;
  - (g) include an indicator of the time taken to respond to complaints; and
  - (h) identify any complaints where recommendations of the Health and Social Care Ombudsman Body were not acted upon during the period of report, giving the reasons why not.
- (4) A relevant service provider annual report must –
- (a) specify the numbers of complaints received in relation to the services provided on Manx Care’s behalf by the relevant service provider;
  - (b) identify the subject matter of those complaints;
  - (c) identify the category of service provided under the Act, the Manx Care Act 2021 or the mandate into which the subject matter of those complaints falls;
  - (d) summarise how they were handled including the outcome of the investigations into those complaints;
  - (e) include a statement outlining changes or improvements to services or procedures as a result of consideration of complaints;
  - (f) include a statement as to the training provided to persons in relation to the handling of complaints;
  - (g) include an indicator of the time taken to respond to complaints; and
  - (h) identify any complaints where recommendations of the Health and Social Care Ombudsman Body were not acted upon, giving the reasons why not.
- (5) A Manx Care annual report must be provided to the Department, by Manx Care, no later than 4 months after the end of the annual reporting period.
- (6) A relevant service provider annual report must be provided to Manx Care, by the relevant service provider, no later than 2 months after the end of the annual reporting period.
- (7) If in pursuance of this regulation a relevant service provider fails to provide any information relevant to any of the matters referred to in paragraph (4)(a) to (h) which Manx Care needs to prepare a Manx Care annual report –
- (a) the service provider must provide an explanation for that failure to Manx Care; and
  - (b) Manx Care may provide that explanation to the Department.
- (8) In this regulation –

“relevant service provider” means a service provider which is providing services under arrangements made with —

- (a) Manx Care in accordance with the Manx Care Act 2021; or
- (b) the Department and novated to Manx Care by virtue of section 13(5) of the Manx Care Act 2021;

“the annual reporting period” means —

- (a) the period beginning with the date on which these Regulations come into operation and ending with the following 31st March; and
- (b) each successive period of 12 months ending with 31st March; and

“annual report” shall be construed accordingly.

## 15 Annual report

- (1) The Department must, in respect of an annual reporting period, prepare a report on the handling, consideration and disposal of complaints during that period.
- (2) The report must be prepared no later than 6 months after the end of the annual reporting period.
- (3) The report must include —
  - (a) a copy of the Manx Care annual report for that annual reporting period;
  - (b) the information referred to in regulation 14(4) insofar as the Department is a service provider during the annual reporting period; and
  - (c) an assessment of the performance in the handling, consideration and disposal of complaints detailed in the Manx Care annual report, including information relating to the implementation by Manx Care of any recommendations made in a report by the Health and Social Care Ombudsman Body under regulation 24.
- (4) The report must be laid before Tynwald as soon as practicable after the report’s preparation.
- (5) The report must be published, by such means as the Department considers appropriate, within one month of being prepared under paragraph (1).
- (6) In this regulation “the annual reporting period” means —
  - (a) the period beginning with the date on which these Regulations come into operation and ending with the following 31st March; and
  - (b) each successive period of 12 months ending with 31st March.

## 16 Training and support

- (1) A service provider must ensure that all staff working on its behalf whose employment duties require them to have contact with members of the public –
  - (a) can provide complainants with information about –
    - (i) its arrangements for dealing with complaints;
    - (ii) the name of its complaints manager; and
    - (iii) the contact details of the complaints manager; and
  - (b) receive relevant training and guidance on –
    - (i) the arrangements for dealing with complaints; and
    - (ii) any services and support which may be available to complainants.
- (2) A service provider must provide to a member of staff who has been affected by the making of a complaint appropriate assistance, support and information, taking into account the circumstances relating to the complaint and that member of staff's needs.

## PART 3 – HANDLING, CONSIDERATION AND DISPOSAL OF COMPLAINTS BY HEALTH AND SOCIAL CARE OMBUDSMAN BODY

### 17 Persons who may make complaints

- (1) A complaint may be made to the Health and Social Care Ombudsman Body by –
  - (a) a person who is receiving or has received health services from a service provider; or
  - (b) a person who is affected, or likely to be affected, by any act, omission or decision of a service provider which provides health services.
- (2) A complaint may be made by a person (in this regulation referred to as a representative) acting on behalf of a person mentioned in paragraph (1) who –
  - (a) has died;
  - (b) is a child;
  - (c) is unable to make the complaint themselves because of physical or mental incapacity; or
  - (d) has requested the representative to act on their behalf.
- (3) Where a representative makes a complaint on behalf of a child, the Health and Social Care Ombudsman Body –



- (a) must not consider the complaint unless it is satisfied that there are reasonable grounds for the complaint being made by a representative instead of the child; and
  - (b) if it is not so satisfied, must notify the representative in writing, and state the reason for its decision.
- (4) This paragraph applies where —
  - (a) a representative makes a complaint on behalf of —
    - (i) a child;
    - (ii) a person who has died; or
    - (iii) a person who is unable to make the complaint themselves because of mental incapacity; and
  - (b) the Health and Social Care Ombudsman Body is satisfied that the representative is not conducting the complaint in the best interests of the person on whose behalf the complaint is made.
- (5) Where paragraph (4) applies —
  - (a) the complaint must not be considered or further considered under these Regulations; and
  - (b) the Health and Social Care Ombudsman Body must notify the representative in writing, and state the reason for its decision.
- (6) In this Part any reference to a complainant includes a reference to their representative within the meaning of this regulation.
- (7) In considering whether the representative is conducting the complaint in a person's best interest under paragraph (4), the Health and Social Care Ombudsman Body must consider, so far as is reasonably ascertainable, whether the representative is acting in a way that is consistent with the person's beliefs, values, wishes and feelings whether expressed orally, in writing or by behaviour in the past or present.

## 18 Matters which may be complained about

A complaint may be made to the Health and Social Care Ombudsman Body if any of conditions A to C are met in relation to that complainant.

### *Condition A*

The complainant —

- (a) has made a complaint to a service provider under Part 2; and
- (b) is not satisfied with the outcome of the investigation of that complaint under Part 2.

### *Condition B*

The complainant —

- (a) has made a complaint to a service provider under Part 2; but

- (b) the investigation of that complaint has not been completed under Part 2 within the period of 3 months starting on the day on which that complaint was made.

*Condition C*

The complainant —

- (a) has made a complaint to a service provider under Part 2; but
- (b) that complaint has not been investigated under Part 2 on the grounds that —
  - (i) the complaint was not made within the time limit in regulation 9, but the complainant believes that the conditions in sub-paragraphs (a) and (b) of regulation 9(2) are met; or
  - (ii) the complaints manager decided the complaint was not required to be investigated under regulation 8(1) and the complainant is not satisfied with that decision.

## **19 Making a complaint**

A complaint must be made in writing but the Health and Social Care Ombudsman Body may, if satisfied that there are special circumstances, consider a complaint made orally.

## **20 Time limit for making a complaint**

- (1) Except as mentioned in paragraph (2), a complaint must be made not later than —
  - (a) 12 months after the date on which the complainant became aware of the matter alleged in the complaint;
  - (b) 6 months after a decision in writing has been issued under regulation 8(2) or 9(3); or
  - (c) 6 months after the response referred to in regulation 11(3) is sent to the complainant under regulation 11(4),whichever is later.
- (2) The Health and Social Care Ombudsman Body may determine that the time limit in paragraph (1) does not apply in the case of a particular complaint.

## **21 Acknowledgement and record of a complaint**

- (1) The Health and Social Care Ombudsman Body must —
  - (a) send to the complainant a written acknowledgement of receipt of the complaint not later than 5 working days after the day on which the secretary receives the complaint; or

- (b) at the request, or with the consent, of the complainant, arrange for the acknowledgment to be made to the complainant by using another form of communication.
- (2) The Health and Social Care Ombudsman Body must send a copy of the complaint, and the written acknowledgment of its receipt, to the service provider that is the subject of the complaint as soon as reasonably practicable.

## 22 Initial action following complaint

- (1) On receiving a complaint the Health and Social Care Ombudsman 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 service provider that is the subject of the complaint;
  - (c) any previous investigation of the complaint, and any action taken as a result of the complaint;
  - (d) the standard considerations listed at paragraph (3) against which the Health and Social Care Ombudsman Body makes a judgement as to whether or not the complaint should be reviewed by it; and
  - (e) any other relevant circumstances.
- (2) For the purpose of considering the views of the complainant under paragraph (1)(a), the complainant must be offered the opportunity to meet with —
  - (a) the Health and Social Care Ombudsman Body;
  - (b) any member of the Health and Social Care Ombudsman Body; or
  - (c) the secretary,to discuss the complaint.
- (3) The standard considerations referred in paragraph (1)(d) are —

### *Standard consideration A*

Whether or not the complainant is directly affected, or likely to be affected, by the subject matter of the complaint.

### *Standard consideration B*

Whether or not the complaint has been made to the Health and Social Care Ombudsman Body within the time limit in regulation 20.

But, if under regulation 20(2) the time limit in regulation 20 does not apply this consideration is to be disregarded.

### *Standard consideration C*

Whether or not the Health and Social Care Ombudsman Body is satisfied that the service provider has reached a resolution with the complainant which is fair and reasonable in the circumstances.

*Standard consideration D*

Whether or not the complaint has been the subject of a decision on the merits in proceedings in any court, tribunal or arbitration.

*Standard consideration E*

Whether or not the complainant has, or had, a right of appeal, reference or review to, or before, a tribunal or any other body or person under any enactment in respect of another complaint the subject matter of which arises out of the same facts as that of the complaint.

*Standard consideration F*

Whether or not the complaint has been properly considered under any enactment or arrangement providing for the resolution of disputes or the investigation of complaints other than under these Regulations.

*Standard consideration G*

Whether or not the complaint would more suitably be dealt with by a court or under an enactment or arrangement referred to in any other standard consideration in this paragraph.

*Standard consideration H*

Whether or not the complaint may be made to the Health and Social Care Ombudsman Body under regulation 18.

- (4) The Health and Social Care Ombudsman Body must give the complainant a written decision notice stating whether it has decided —
- (a) to take no further action in respect of the complaint;
  - (b) to review the decision on the complaint under Part 2 to recommend what action (if any) may be taken to resolve the complaint; or
  - (c) to refer the complaint to a health or social care regulatory body.

This is subject to paragraph (7).

- (5) The decision notice must be sent to the complainant —
- (a) before the end of the period of 20 working days beginning with the day on which the complaint was made; or
  - (b) if, before the end of the period referred to in sub-paragraph (a) —
    - (i) the assessment referred to in paragraph (1) has not been completed; or
    - (ii) the meeting referred to in paragraph (2) has not taken place, as soon as is reasonably practicable after the assessment has been carried out and, in any case within the period of 80 working days starting on the

day on which the Health and Social Care Ombudsman Body receives the complaint.

- (6) If a decision notice is not sent within the period referred to in paragraph (5)(a), the Health and Social Care Ombudsman Body must notify the complainant in writing accordingly explaining why that is the case and specifying when the complainant can expect to receive such a notice.
- (7) The decision notice must –
  - (a) include the reasons for the Health and Social Care Ombudsman Body’s decision and a summary of its understanding of the complaint;
  - (b) in the case of a decision referred to in paragraph (4)(a), include information about what further action the complainant might reasonably take in relation to the complaint, if applicable; and
  - (c) be sent to –
    - (i) the complainant;
    - (ii) the service provider that is the subject of the complaint;
    - (iii) if the service provider that is the subject of the complaint is neither Manx Care nor the Department, Manx Care; and
    - (iv) if the service provider that is the subject of the complaint is not the Department, the Department.
- (8) The Health and Social Care Ombudsman Body must keep a record of the decision referred to in paragraph (4).

## **23 Complaint review**

- (1) If the Health and Social Care Ombudsman Body decides to review a complaint, it may require any person or body to produce such information and documents as it considers necessary to enable the complaint to be considered properly.
- (2) A requirement under paragraph (1) must be made in writing.
- (3) The Health and Social Care Ombudsman Body cannot require the production of information which –
  - (a) is confidential and relates to a living individual unless the individual to whom the information relates has consented to its disclosure and use for the purposes of the review; or
  - (b) is the subject of legal professional privilege.
- (4) The person or body required to produce information under paragraph (1) must provide that information in good order, or an explanation for not doing so, not later than one month after the day on which the request was made and in accordance with the requirement.

- (5) If the person or body required to produce information under paragraph (1) does not do so in accordance with paragraph (4), the person or body must –
  - (a) explain to the Health and Social Care Ombudsman Body why the person or body has not done so; and
  - (b) agree with the Health and Social Care Ombudsman Body a reasonable period of time within which to do so, not exceeding 2 months following the expiry of the one-month period referred to in paragraph (4).
- (6) Subject to paragraphs (7) and (8), the Health and Social Care Ombudsman Body may govern its own procedure in any manner which seems to it to be appropriate and may take such advice as appears to it to be required.
- (7) The Health and Social Care Ombudsman Body may convene a hearing to take oral evidence or advice from any person who wishes to give additional evidence or advice to it.
- (8) A person giving evidence before the Health and Social Care Ombudsman Body hearing may be accompanied by another person.
- (9) The Health and Social Care Ombudsman Body must ensure that the complainant is kept informed about –
  - (a) the date and time of any hearing; and
  - (b) the identity of any person from whom the Health and Social Care Ombudsman Body proposes to take evidence or advice.
- (10) The Health and Social Care Ombudsman Body must establish and operate a complaints procedure in respect of the exercise of its functions under this Part in the handling, consideration and disposal of complaints made to it and publish information outlining that procedure.

## **24 Report following complaint investigation and record-keeping**

- (1) If the Health and Social Care Ombudsman Body reviews a complaint under this Part, it must prepare a written report of its review, within a period consistent with its published service standards, which –
  - (a) summarises the nature and substance of the complaint;
  - (b) describes the review and summarises its conclusions, including any findings of fact, the Health and Social Care Ombudsman Body's opinion of those findings and its reasons for that opinion;
  - (c) recommends what action, if any, 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) If the Health and Social Care Ombudsman Body does not prepare the report within the time limit in paragraph (1), the Health and Social Care

Ombudsman Body must notify the complainant in writing explaining why it has not done so and when it expects to do so.

- (3) The report may include any other recommendations which the Health and Social Care Ombudsman Body considers would in its opinion lead to any improvements, or which would otherwise be effective for the purpose of resolving the complaint.
- (4) The report must not include any information from which the identity of a living individual could be ascertained unless the individual consents to that information being included in the report.
- (5) The report must be signed by the chairperson and sent without delay to —
  - (a) the complainant;
  - (b) the service provider that is the subject of the complaint;
  - (c) if the service provider that is the subject of the complaint is neither Manx Care nor the Department, Manx Care; and
  - (d) if the service provider that is the subject of the complaint is not the Department, the Department.
- (6) The Health and Social Care Ombudsman Body must publish the report on the Health and Social Care Ombudsman Body's website within one month of it being sent to the complainant under paragraph (5)(a).

This is subject to paragraph (7).
- (7) The requirement to publish a report under paragraph (6) does not apply to any part of the report if, in the opinion of the Health and Social Care Ombudsman Body, publishing that part —
  - (a) could jeopardise the safety of any person; or
  - (b) would breach —
    - (i) data protection legislation; or
    - (ii) any duty of care or confidence imposed by statute or otherwise.
- (8) The Health and Social Care Ombudsman Body must keep any information relating to a complaint for a period of 10 years beginning on the day the report is sent to the complainant.

## **25 Department's assurance of the implementation of recommendations**

- (1) On receiving a report under regulation 24(5), Manx Care must prepare a written statement of —
  - (a) how it proposes to give effect to any recommendations made in the report; and
  - (b) any other action which it proposes to take in response to the report, and the period within which it proposes to do so.

- (2) Manx Care must send the written statement to the Department.
- (3) Manx Care must publish the written statement on its website excluding any information from which the identity of a living individual could be ascertained.
- (4) If Manx Care proposes not to give effect to any recommendation made in the report —
  - (a) it must include in the written statement its reasons for not giving effect to the recommendation; and
  - (b) the Department may give a direction to Manx Care requiring Manx Care to give effect to the recommendation.
- (5) A direction given under paragraph (4)(b) —
  - (a) must be —
    - (i) in writing; and
    - (ii) published by the Department; and
  - (b) without prejudice to any other provision of these Regulations, may —
    - (i) specify the period within which; and
    - (ii) make suggestions (which are not binding) as to how, the recommendation made in the report received under regulation 24(5)(b) is to be given effect.
- (6) But paragraph (5)(a) does not require the Department to publish part of a direction if—
  - (a) it could refuse to disclose it in response to a request under the Freedom of Information Act 2015; or
  - (b) its disclosure is prohibited by any enactment.
- (7) The Department must keep under review Manx Care's performance in implementing any recommendation made in a report and any other actions outlined in the written statement.

## 26 Annual report

- (1) The Health and Social Care Ombudsman Body must prepare an annual report each annual reporting period on the discharge of its functions under this Part during that period.
- (2) The annual report must include —
  - (a) information about how long reviews that were completed in the annual reporting period took to be concluded;
  - (b) information about how many of those reviews took more than 6 months to be completed;



- (c) information about the action being taken with a view to all reviews being concluded within 12 months;
  - (d) information as to whether the Health and Social Care Ombudsman Body has taken any advice from any person under regulation 23(7) and the identity of that person;
  - (e) an anonymised summary of reviews completed in the annual reporting period;
  - (f) a report on all outstanding recommendations made by the Health and Social Care Ombudsman Body in respect of any reviews completed in the annual reporting period, including for how long those recommendations have been outstanding;
  - (g) information about any complaints made in the annual reporting period relating to how the Health and Social Care Ombudsman Body has discharged its functions;
  - (h) information about any improvements made to the arrangements for handling complaints under this Part by the Health and Social Care Ombudsman Body arising from the operation of the complaints procedure referred to in regulation 23(10); and
  - (i) information about any training provided to members of the Health and Social Care Ombudsman Body in the annual reporting period.
- (3) The annual report must be submitted to the Department, by the Health and Social Care Ombudsman Body, no later than 31 August.
- (4) The Department must lay the annual report before Tynwald as soon as practicable.
- (5) The annual report must be published, by such means as the Department considers appropriate, within one month of being laid before Tynwald under paragraph (4).
- (6) The annual report must be made available free of charge to any person on request.
- (7) In this regulation “the annual reporting period” means –
- (a) the period beginning with the date on which these Regulations come into operation and ending with the following 31st March; and
  - (b) each successive period of 12 months ending with 31st March,
- and “annual report” shall be construed accordingly.

## 27 Publicity and code of practice

- (1) The Health and Social Care Ombudsman Body must make information available to the public as to –
- (a) the handling, consideration and disposal of complaints under this Part;

- (b) how further information about the handling, consideration and disposal of complaints under this Part may be obtained;
  - (c) how the secretary can be contacted; and
  - (d) its membership.
- (2) The Health and Social Care Ombudsman Body must issue a code of practice in relation to the handling, consideration and disposal of complaints by it under this Part.
- (3) A code of practice issued by the Health and Social Care Ombudsman Body must be such as to ensure that—
- (a) complaints are welcomed in a positive way;
  - (b) complaints are dealt with speedily and efficiently;
  - (c) complaints are investigated thoroughly and fairly;
  - (d) complainants are treated with respect and courtesy; and
  - (e) complainants receive a timely and appropriate response and are given fair and accountable responses.
- (4) The Health and Social Care Ombudsman Body must have regard to the code of practice when reviewing a complaint.
- (5) The Health and Social Care Ombudsman Body may, from time to time, revise its code of practice.

## PART 4 – CONSEQUENTIAL AMENDMENTS

### 28 Amendment of the National Health Service (Pharmaceutical Services) Regulations 2005

- (1) The National Health Service (Pharmaceutical Services) Regulations 2005<sup>14</sup> are amended as follows.
- (2) In Schedule 1 (terms of service of pharmacists), Part 4, in paragraph 30 for “as if the National Health Service (Complaints) Regulations 2004 applied to him” substitute **23** in accordance with Part 2 of the National Health Service (Complaints) Regulations 2022 **22**.

### 29 Amendment of the National Health Service (General Ophthalmic Services) Regulations 2004

- (1) The National Health Service (General Ophthalmic Services) Regulations 2004<sup>15</sup> are amended as follows.
- (2) In Schedule 1 (terms of service) —

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<sup>14</sup> SD 727/05. SD 727/05 was amended by SD 2019/0416, SD 2019/0418 and SD 2020/0588.

<sup>15</sup> SD 18/04.

- (a) for paragraph 9 substitute —
- 9. A contractor shall make arrangements for the handling, consideration and disposal of complaints made by or on behalf of his patients or former patients in accordance with Part 2 of the National Health Service (Complaints) Regulations 2022. 9; and
- (b) omit paragraphs 10 and 15.

## **PART 5 – REVOCATIONS AND TRANSITIONAL AND SAVINGS PROVISIONS**

### **30 Revocations**

Notwithstanding regulations 31 to 34, the following are revoked—

- (a) the 2004 Complaints Regulations; and
- (b) the 2004 Independent Review Body Regulations.

### **31 Unresolved complaints made to the Department, Manx Care or a primary care provider under the 2004 Complaints Regulations**

- (1) Despite the revocation of the 2004 Complaints Regulations, where a person has made a complaint to the Department, Manx Care or a primary care provider under the 2004 Complaints Regulations and either —
  - (a) no response has been sent under regulation 10 of the 2004 Complaint Regulations; or
  - (b) a response has been sent under regulation 10 and the person has requested a review of the complaint by Manx Care under regulation 10A of those Regulations but a response has not been provided under regulation 10B of those Regulations,the 2004 Complaints Regulations continue to apply to that complaint.
- (2) Where paragraph (1) applies and a person wishes to request the Independent Review Body to consider their complaint under regulation 11 of the 2004 Complaint Regulations, the person may request the Health and Social Care Ombudsman Body to treat the complaint as one under regulation 19 of these regulations.

### **32 Unresolved complaints made to an independent provider under the 2004 Complaints Regulations**

Despite the revocation of the 2004 Complaints Regulations, where —

- (a) a person is not satisfied with the result of an investigation by an independent provider with whom Manx Care has made arrangements (see regulation 2(4) of the 2004 Complaints Regulations); and

- (b) the person has requested a review of the complaint by Manx Care under regulation 10A(2) of the 2004 Complaints Regulations, but a response has not been provided under regulation 10B of those Regulations,

the 2004 Complaints Regulations continue to apply to that complaint.

### **33 Unresolved complaints made to the Independent Review Body under the 2004 Complaints Regulations: investigation begun**

- (1) Despite the revocation of the 2004 Complaints Regulations and the 2004 Independent Review Body Regulations, where —
  - (a) a complaint has been made under the 2004 Complaints Regulations to the Independent Review Body established under regulation 2 of the 2004 Independent Review Body Regulations; and
  - (b) the Independent Review Body has assessed the nature and substance of the complaint and decided how it should be handled under regulation 12(1) of the 2004 Complaints Regulations but has not disposed of it,

the 2004 Complaints Regulations and the 2004 Independent Review Body Regulations shall continue to apply to that complaint.

- (2) If the person who has made the complaint, the Independent Review Body and the Health and Social Care Ombudsman Body agree that a complaint referred to in paragraph (1) should be dealt with by the Health and Social Care Ombudsman Body, the complaint shall be dealt with under regulation 19 of these regulations.

### **34 Unresolved complaints made to the Independent Review Body under the 2004 Complaints Regulations: investigation not begun**

Despite the revocation of the 2004 Complaints Regulations, where —

- (a) a complaint has been made under the 2004 Complaints Regulations to the Independent Review Body established under regulation 2 of the 2004 Independent Review Body Regulations; and
- (b) immediately before these Regulations come into operation, the Independent Review Body has not assessed the nature and substance of the complaint or decided how it should be handled under regulation 12(1) of the 2004 Complaints Regulations (or otherwise disposed of it),

the complaint is to be treated for all purposes as if it had been made to the Health and Social Care Ombudsman Body under Part 3 of these Regulations.

**MADE 30 JUNE 2022**

**LAWRIE HOOPER**  
*Minister for Health and Social Care*

*EXPLANATORY NOTE**(This note is not part of the Regulations)*

These Regulations revoke and replace the National Health Service (Complaints) Regulations 2004 and the National Health Service (Independent Review Body) Regulations 2004. They have 4 Parts.

Part 1 is introductory. Parts 2 and 3 make provision for the handling, consideration and disposal of complaints about the provision of certain health services and about other matters.

Part 2 of the Regulations sets out the process to be followed in relation to a complaint made to a body that has provided health services (called a service provider in the Regulations) under the mandate issued by the Department of Health and Social Care to Manx Care. This may include Manx Care, or any other body that is providing services under an arrangement with Manx Care and the Department of Health and Social Care (but only in certain circumstances). Complaints can be made by adults, children or a representative of the adult or child (regulation 6).

Part 3 of the Regulations sets out the process to be followed in relation to a complaint made to the Health and Social Care Ombudsman Body. Regulation 18 sets out the complaints that can be made to the Health and Social Care Ombudsman Body and covers where a person is not satisfied with the outcome of the investigation under Part 2 of the Regulations, the investigation of a complaint made under Part 2 has not been completed within 3 months of it being made (this is deliberately before the 6 month backstop for the final response being sent under Part 2 to encourage prompt responses to be sent) or if a complaint has been made under Part 2 but has not been investigated and the complainant is not satisfied with the explanation given for the complaint not being investigated.

Part 4 makes consequential amendments and Part 5 contains transitional and savings provisions and revocations.