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NATIONAL HEALTH SERVICE (COMPLAINTS) REGULATIONS 2021

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Statutory Document No. 20XX/XXXX

C

National Health Service Act 2021

NATIONAL HEALTH SERVICE (COMPLAINTS) REGULATIONS 2021

*Laid before Tynwald:**Coming into Operation:*

The Department of Health and Social Care makes the following Regulations under section 38 of the National Health Service Act 2001¹ after satisfying the requirements of section 42(5) of the National Health Service Act 2001².

PART 1 – INTRODUCTION

1 Title

These Regulations are the National Health Service (Complaints) Regulations 2021.

2 Commencement

These Regulations come into operation on [TBC]³.

3 Interpretation

(1) In these Regulations –

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

¹ Section 38 of the National Health Service Act 2001 was substituted by SD 2021/XXXX.

² 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.

³ Under section 42(2) of the National Health Service Act 2001 Regulations made under the National Health Service Act 2001 (other than those making any provision under sections 32 to 36 of the National Health Service Act 2001) shall be laid before Tynwald as soon as may be after they are made and if Tynwald at the sitting at which they are laid or the next following sitting resolves that they be annulled, they shall cease to have effect.

“the 2004 Regulations” means the National Health Service (Complaints) Regulations 2004⁴;

“adult” means an individual who has attained the age of 18;

“applied GDPR” and **“GDPR”** have the meanings given in the Data Protection (Application of GDPR) Order 2018⁵;

“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 as applicable;

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

“disciplinary proceedings” means any procedure for disciplining employees adopted by the service provider;

“Health and Social Services Independent Review Body” means the body constituted under section 26A of the Social Services Act 2011 and **“chairperson”** means the chairperson of that body;

“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 2002⁶ (of Parliament);

“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;

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

“secretary” means a person appointed by the Public Services Commission to provide secretariat services to the Health and Social Services Independent Review 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; and

“working day” means any day other than a Saturday, a Sunday, Christmas Day, Boxing Day, Good Friday or a day which is a bank holiday under the Bank Holidays Act 1989.

(2) In these Regulations **“service provider”** means —

(a) Manx Care;

(b) the Department, but only if it has been given a direction under section 30(6) of the Manx Care Act 2021 (failure by Manx Care to discharge any of its functions); and

⁴ SD 216/04. SD 216/04 was amended by SD 2021/0067.

⁵ SD2018/0143.

⁶ 2002 c.17.

- (c) any other person or body which is providing services under arrangements made with –
 - (i) Manx Care in accordance with the Manx Care Act 2021; or
 - (ii) the Department in accordance with the Act and transferred to Manx Care under section 13(5) of the Manx Care Act 2021 (Manx Care and its general functions).
- (3) In these Regulations, unless the context or subject matter indicates or requires otherwise, “**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 Services Independent Review Body under Part 3.

PART 2 – HANDLING AND CONSIDERATION OF COMPLAINTS BY SERVICE PROVIDERS

4 Arrangements for the handling and consideration of complaints

- (1) Each service provider must make arrangements (“arrangements for dealing with complaints”) in accordance with this Part for the handling and consideration of complaints.
- (2) The arrangements for dealing with complaints must be accessible and 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;
 - (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 and considering 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 service provider to act on behalf of the responsible person.
- (3) The functions of the complaints manager may be performed by any person authorised by the service provider to act on behalf of the complaints manager.
- (4) The responsible person is to be—
- (a) in the case of the Department, the person who acts as the chief executive officer of the Department;
 - (b) in the case of Manx Care, the person who acts as the chief executive officer of Manx Care;
 - (c) in the case of any other service provider, the person who acts as 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) Without prejudice to paragraph (1)(b), the complaints manager may be—
- (a) a person who is not an employee of the service provider;
 - (b) the same person as the responsible person;
 - (c) a complaints manager designated by another service provider under paragraph (1)(b).
- (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 under —
 - (i) the Act;
 - (ii) the Manx Care Act 2021; or
 - (iii) the mandate; or
 - (b) any person who is affected, or likely to be affected, by the action, omission or decision of a service provider which provides health services under —
 - (i) the Act;
 - (ii) the Manx Care Act 2021;
 - (iii) the mandate,which is the subject of the complaint.
- (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) In the case of a person mentioned in paragraph (1) 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 the welfare of the person mentioned in paragraph (1) 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 welfare of a person mentioned in paragraph (1) or is unsuitable to act as a representative, the complaints manager must notify that person in writing, stating the complaints manager's 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 Manx Care, the representative must be a person authorised by Manx Care.
- (6) In this Part any reference to a complainant includes a reference to their representative within the meaning of this regulation.

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 under —

- (a) Part 2 or 3 of the Act;
- (b) the Manx Care Act 2021; or
- (c) the mandate.

8 Complaints not required to be dealt with

- (1) 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 is the same as that of a complaint that has previously been made and resolved in accordance with sub-paragraph (c);
 - (e) a complaint the subject matter of which has previously been investigated under—
 - (i) these Regulations;
 - (ii) the 2004 Regulations; or
 - (iii) a relevant complaints procedure;
 - (f) a complaint arising out of the service provider's alleged failure to comply with a data subject request under the applied GDPR;
 - (g) 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
 - (h) a complaint about which the service 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.
- (2) Subject to paragraph (3), where a complaint is a complaint specified in paragraph (1), and a service provider makes a decision to that effect, the service provider must as soon as reasonably practicable notify the complainant in writing of its decision and the reason for its decision.
- (3) Paragraph (2) does not apply to a complaint specified in sub-paragraph (c) of paragraph (1).

- (4) 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) Except as mentioned in paragraph (2), 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.

10 Procedure before investigation

- (1) A complaint may be made orally, in writing or electronically.
- (2) Where a person wishes to make a complaint under this Part, the person 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 a complaint not later than 5 working days after the day on which the complaint was received.
- (5) The acknowledgement must be made in writing.
- (6) Where a complaint was made orally, the acknowledgement must be accompanied by the written record mentioned in paragraph (2)(a) with an invitation to the complainant to sign and return it.
- (7) 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 and consideration of the complaint; and
 - (e) if appropriate, require the complainant to produce further information or documents to the complaints manager on behalf of the service provider in writing to enable the complaint to be properly considered.
- (8) The complaints manager must send a copy of the complaint and the complaints manager's acknowledgement to any person identified in the complaint as the subject of the complaint.

11 Investigation and response

- (1) The complaints manager must –
- (a) investigate the complaint in a manner appropriate to resolve it speedily and efficiently; and
 - (b) during the investigation, keep the complainant informed as to the progress of the investigation no later than 20 working days after the day on which the complaint was made and thereafter on a regular basis.
- (2) As part of the investigation, the complaints manager must –
- (a) invite the complainant to attend a meeting to discuss the complaint; and
 - (b) offer the complainant an opportunity to meet with a relevant health or social care professional who is familiar with the complaint and is qualified to answer questions about the services provided by, or the action, omission or decision of, the service provider which is the subject 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);
 - (d) summarises –
 - (i) its conclusions,

- (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.
- (5) If the service provider does not send the complainant a response within the time limit in paragraph (4), the service provider must notify the complainant in writing accordingly and explain the reasons why and when the complainant can expect to receive the response.
- (6) The response must –
 - (a) notify the complainant of the complainant's right to refer the complaint to the Health and Social Services Independent Review Body; and
 - (b) provide the contact details for that body.
- (7) A copy of the response must be sent to any other person to whom a copy of the complaint was sent under regulation 10(8).

12 Learning from complaints

A service provider must –

- (a) ensure that any remedial action needed is taken promptly (including, whenever 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 and consideration of complaints by the service provider;
- (e) where a complaint indicates that the service provider has not complied with any relevant provision of Code of Conduct issued by a health or social care relevant regulatory body or with any other relevant professional requirement or expectation of such a body, the service provider must consider referring the complaint to that body and, if appropriate, do so; and

- (e) 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 2021⁷.

13 Publicity and guidance

- (1) Each service provider must make information available to the public as to—
 - (a) its arrangements for dealing with complaints; and
 - (b) how further information about those arrangements may be obtained.
- (2) The Department must provide face-to-face 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 offer guidance and support such as to ensure that people who are dissatisfied with the service received from Manx Care receive —
 - (a) assistance to resolve an issue whose subject matter is one 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 to make a complaint.

14 Monitoring

- (1) For the purpose of monitoring the arrangements under this Part Manx Care must prepare and provide to the Department an annual report.
- (2) The report mentioned in paragraph (1) must —
 - (a) specify the numbers of complaints received in relation to the services provided under the mandate by —
 - (i) Manx Care; and
 - (ii) any other service provider which is providing services under arrangements made with Manx Care, in accordance with the Manx Care Act 2021, or made with the Department in accordance with the Act and transferred to Manx Care by virtue of section 13(5) of the Manx Care Act 2021;
 - (b) identify the subject matter of those complaints;
 - (c) summarise how they were handled including the outcome of the investigations into those complaints;

⁷ SD 2021/0069.

- (d) include a statement outlining changes or improvements to services or procedures as a result of consideration of complaints;
 - (e) include an indicator of the time taken to respond to complaints; and
 - (f) identify any complaints where recommendations of the Health and Social Services Independent Review Body were not acted upon, giving the reasons why not.
- (3) The report mentioned in paragraph (1) must be provided to the Department within 3 months of the end of each financial year.
- (4) If in pursuance of this regulation a service provider referred to in paragraph (2)(a)(ii) fails to provide any information relevant to any of the matters referred to in paragraph (2)(a) to (f) which Manx Care needs to prepare the 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.

15 Annual report

- (1) The Department must prepare an annual report for each year on the handling and consideration of complaints under this Part during the report period no later than 6 months after the end of the report period.
- (2) The report must be laid before Tynwald as soon as practicable after its preparation.
- (3) In this regulation “the report 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

The service provider must ensure that all staff working on its behalf whose employment duties require them to have face-to-face 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 address at which the complaints manager can be contacted; 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.

PART 3 – HANDLING AND CONSIDERATION OF COMPLAINTS BY HEALTH AND SOCIAL SERVICES INDEPENDENT REVIEW BODY

17 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 under —
 - (i) the Act;
 - (ii) the Manx Care Act 2021; or
 - (iii) the mandate; or
 - (b) any person who is affected, or likely to be affected, by the action, omission or decision of a service provider which provides health services under —
 - (i) the Act;
 - (ii) the Manx Care Act 2021;
 - (iii) the mandate,which is the subject of the complaint.
- (2) A complaint may also be made by a person (in this regulation referred to as a representative) acting on behalf of a person mentioned in paragraph (1) if that person —
 - (a) has died;
 - (b) is a child;
 - (c) is unable by reason of a physical or mental incapacity to make the complaint; or
 - (d) has requested the representative to act on their behalf.
- (3) In the case of a person mentioned in paragraph (1) who has died or who is incapable, the representative must be a relative or other person who, in the opinion of the Health and Social Services Independent Review Body had, or has, a sufficient interest in the person's welfare and is a suitable person to act as a representative.
- (4) If the Health and Social Services Independent Review Body is of the opinion that a person —
 - (a) does, or did, not have a sufficient interest in the person's welfare; or
 - (b) is unsuitable to act as a representative,the Health and Social Services Independent Review Body must notify that person in writing, stating its reasons.
- (5) In the case of a child, the representative must be —

- (a) a parent, or other person who has parental responsibility for the child (within the meaning of the Children and Young Persons Act 2001);
 - (b) a carer for the child; or
 - (c) any other person acting on behalf of the child who has an interest in the child's welfare.
- (6) In this Part any reference to a complainant includes a reference to their representative within the meaning of this regulation.

18 Complaints which may be made

A complaint may be made to the secretary of the Health and Social Services Independent Review Body if any of conditions A to C is met in relation to that person.

Condition A

The person —

- (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 person—

- (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 6 months after the date on which that complaint was made.

Condition C

The person—

- (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 the complaint was not made within the time limit in regulation 9, but the person believes that the conditions in subparagraphs (a) and (b) of regulation 9(2) are met.

19 Procedure before consideration of complaint

- (1) A complaint must be —
 - (a) made in writing on the form provided by the Health and Social Services Independent Review Body for the purpose of making such a complaint (“the approved form”);
 - (b) completed in accordance with the instructions on that form; and
 - (c) given or sent to the secretary, by electronic or other means.

- (2) The approved form must be made freely available and without charge, and be able to be downloaded from a website.
- (3) Where a complaint is made otherwise than in accordance with paragraph (1) –
 - (a) the secretary must record the detail of the complaint on the approved form insofar as is possible from the information contained within the complaint; and
 - (b) return the approved form (insofar as the detail of the complaint is recorded on it) to the complainant for the approved form to be reviewed, completed and resubmitted in accordance with paragraph (1).
- (4) The secretary must make a written record of the date on which a complaint –
 - (a) made in accordance with paragraph (1); or
 - (b) resubmitted in accordance with paragraph (3),is received by the secretary.

20 Time limit for making a complaint

- (1) Except as mentioned in paragraph (2), a complaint must be made not later than 12 months after the date on which the complainant became aware of the matter alleged in the complaint.
- (2) The chairperson 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 secretary must send to the complainant a written acknowledgement of a complaint not later than 5 working days after the day on which the secretary receives the complaint.
- (2) The secretary must send a copy of the complaint and the acknowledgment 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 Services 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 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) a set of standard considerations (see paragraph (3)) against which the Health and Social Services Independent Review Body makes a judgement as to whether or not the complaint should be reviewed by it; and
 - (e) any other relevant circumstances.
- (2) In 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 Services Independent Review Body;
 - (b) any member of the Health and Social Services Independent Review Body; or
 - (c) the secretary,

to discuss the nature of the complaint and the complaints which may be made to the Health and Social Services Independent Review Body under regulation 18.

- (3) The standard considerations referred in paragraph (1)(d) are –

Standard consideration A

Whether or not the complainant is directly affected by the subject matter of the complaint.

Standard consideration B

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

But, if under regulation 20(2) the time limit in regulation 20 does not apply in the case of the complaint, standard consideration B is to be disregarded.

Standard consideration C

Whether or not the Health and Social Services Independent Review 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.

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 is the same 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 complainant has exhausted the service provider's internal complaints procedure.

But if the service provider has not responded to the complainant in relation to a complaint within 6 months of receiving the complaint standard consideration H is to be disregarded.

- (4) The Health and Social Services Independent Review Body must notify the complainant not later than 20 working days after the day on which it receives the complaint whether it has decided —
- (a) to take no further action in respect of the complaint;
 - (b) to review the previous investigation of the complaint under Part 2 to recommend what action 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 (5).
- (5) If the meeting referred to in paragraph (2) does not take place within the period of 20 working days referred to in paragraph (4) at the request of the complainant, the Health and Social Services Independent Review Body must send the notification as soon as reasonably practicable after the meeting.
- (6) Notice of the decision referred to in paragraph (4) must —
- (a) include the reasons for its decision;
 - (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; and
 - (iii) the Department.
- (7) The secretary must record the decision referred to in paragraph (4) in the minutes of the Health and Social Services Independent Review Body's meetings.

23 Complaint review

- (1) If the Health and Social Services Independent Review Body decides to review a complaint under regulation 22(4)(b), it may require any person

or body to produce such information and documents as the Health and Social Services Independent Review Body considers necessary in order to enable the complaint to be considered properly.

- (2) A requirement under paragraph (1) must —
 - (a) be made in writing or electronically; and
 - (b) explain why the information or documents requested are relevant to the consideration of the complaint.
- (3) The Health and Social Services Independent Review Body must not make a requirement under paragraph (1) for 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) For the purposes of paragraph (3)(a), consent may be either express or implied.
- (5) 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 6 weeks after the day on which the request was made and in accordance with the requirement.
- (6) If the person or body required to produce information under paragraph (1) does not provide that information in accordance with paragraph (5), the person or body must —
 - (a) provide an explanation to the Health and Social Services Independent Review Body as to why it has not done so; and
 - (b) agree with the Health and Social Services Independent Review Body a reasonable period of time within which it will do so.
- (7) The Health and Social Services Independent Review Body may conduct its review of a complaint in any manner which seems to it to be appropriate and may take such advice as appears to it to be required.
- (8) The Health and Social Services Independent Review Body may convene a hearing to take oral evidence or advice from any person who wishes to give additional evidence or advice to it.
- (9) A person giving evidence before the Health and Social Services Independent Review Body hearing may be accompanied by another person.
- (10) The Health and Social Services Independent Review Body must ensure that the complainant is kept informed generally and in particular about —
 - (a) the composition of the Health and Social Services Independent Review Body;
 - (b) the date and time of any hearing; and

- (c) the identity of any person from whom the Health and Social Services Independent Review Body proposes to take evidence or advice.
- (11) The Health and Social Services Independent Review Body must establish and operate a complaints procedure in respect of the exercise of its functions under this Part in the handling and consideration of complaints made to it.

24 Report following complaint review

- (1) If the Health and Social Services Independent Review Body reviews a complaint under this Part it must, within 6 months, prepare a written report of its reviews 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 Services Independent Review 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) The report may include any other recommendations which the Health and Social Services Independent Review Body considers would in their opinion lead to any improvements, or which would otherwise be effective for the purpose of resolving the complaint.
- (3) The report must be signed by the chairperson and sent to –
- (a) the complainant;
 - (b) Manx Care;
 - (c) the Department; and
 - (d) the service provider that was the subject of the complaint, if not Manx Care or the Department.

This is subject to paragraph (4).

- (4) The Health and Social Services Independent Review Body must redact the report to ensure that any confidential information from which the identity of a living individual can be ascertained is not disclosed without the express consent of the individual.
- (5) The Health and Social Services Independent Review Body must publish the report as redacted in accordance with paragraph (4) on the Health and Social Services Independent Review Body's website.

25 Department's assurance of the implementation of recommendations

- (1) On receiving a report under regulation 24(3)(b), Manx Care must prepare a written statement of —
 - (a) how it proposes to give effect to any recommendations made in that report;
 - (b) any other action which it proposes to take in response to —
 - (i) the report received; and
 - (ii) any suggestions made in a report received which it chooses to implement,and the period within which it proposes to do so.
- (2) Manx Care must send the written statement to the Department.
- (3) The Department must keep under review Manx Care's performance in implementing any recommendation made in a notice of decision or report and any other actions outlined in the written statement under paragraph (1).

26 Annual report

- (1) The Health and Social Services Independent Review Body must prepare an annual report in May of each year on the discharge of its functions under this Part during the report period.
- (2) The annual report must include information about —
 - (a) how long reviews that were completed in the report period took to be concluded;
 - (b) how many of those reviews took more than 6 months to be completed;
 - (c) the action being taken with a view to all reviews being concluded within 12 months;
 - (d) an anonymised summary of reviews completed in the report period;
 - (e) a report on all outstanding recommendations made by the Health and Social Services Independent Review Body in respect of any reviews completed in the report period;
 - (f) any complaints made in the report period relating to how the Health and Social Services Independent Review Body has discharged its functions; and
 - (g) any improvements made by the Health and Social Services Independent Review Body arising from the operation of the complaints procedure referred to in regulation 23(11).
- (3) The annual report must be submitted to the Department to be laid before the next sitting of Tynwald.

- (4) The annual report must be published on the Department's website.
- (5) In this regulation "the report 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.

27 Publicity

The Health and Social Services Independent Review Body must make information available to the public as to —

- (a) the handling and consideration of complaints under this Part; and
- (b) how further information about the handling and consideration of complaints under this Part may be obtained.

PART 4 – TRANSITIONAL AND SAVINGS PROVISIONS AND REVOCATIONS

28 Transitional and savings provisions: novated contracts and agreements

- (1) This paragraph applies to a service provider (A) —
 - (a) with whom the Department entered into a contract or agreement referred to in section 13(5) of the Manx Care Act 2021 which is deemed to be novated to Manx Care under that section; and
 - (b) which, at the time of novation, in pursuance of any provision of the mandate, was not required to establish and operate an internal complaints procedure in respect of the services A provides under that contract or agreement under paragraph 2(b) of Schedule 2 to the Manx Care Act 2021.
- (2) Nothing in these Regulations applies to A until the earlier of the following days —
 - (a) the first day on which the contract or agreement referred to in paragraph (1) is renewed or re competed; and
 - (b) the day after the last day of the period of 6 months beginning on the day on which these Regulations come into operation.

29 Transitional and savings provisions: service providers required to establish and operate an internal complaints procedure but to whom the 2004 Regulations did not apply

- (1) This regulation applies to a service provider (B) —
 - (a) with whom the Department has entered into an agreement under section 17 of the Manx Care Act 2021;

- (b) who, in pursuance of any provision of the mandate, is required to establish and operate an internal complaints procedure in respect of the services B provides under that contract or agreement under paragraph 2(b) of Schedule 2 to the Manx Care Act 2021; and
 - (c) immediately before the day on which these Regulations come into operation, to whom the 2004 Regulations did not apply.
- (2) Nothing in these Regulations applies to B until the day after the last day of the period of 6 months beginning on the day on which these Regulations come into operation.

30 **Transitional provisions: unresolved complaints made under the 2004 Regulations**

- (1) This paragraph applies if —
- (a) a complainant has, in accordance with the 2004 Regulations, requested the Independent Review Body to consider a complaint made by the complainant in accordance with the 2004 Regulations; and
 - (b) immediately before these Regulations come into operation, none of the actions referred to in regulation 12(2)(a) to (c) of the 2004 Regulations has been taken by the Independent Review Body in relation to the complaint.
- (2) If paragraph (1) applies the complaint referred to in paragraph (1) is to be treated for all purposes as if it had been made to the Health and Social Services Independent Review Body under Part 3 and not to the Independent Review Body in accordance with the 2004 Regulations.
- (3) In this Part “**complainant**” and “**Independent Review Body**” have the meanings given to those phrases in the 2004 Regulations.

31 **Revocations**

The following are revoked —

- (a) the 2004 Regulations; and
- (b) the National Health Service (Independent Review Body) Regulations 2004⁸.

⁸ SD 679/04. SD 679/04 was amended by SD 2021/0068.

MADE

Minister for Health and Social Care

Draft 26-8-21

*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 and consideration of complaints about the provision of certain health services and about other matters. Part 4 contains transitional and savings provisions and revocations.

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