



ISLE OF MAN GOVERNMENT

DEPARTMENT OF HEALTH AND SOCIAL CARE

COMPLAINTS MODERNISATION

Part 1: Consultation on short term changes – by
Regulation

Issue date: 6 September 2021

Closing date: 18 October 2021

The purpose of this consultation

This consultation is one of two issued by the Department for Health and Social Care (“**the Department**”) in conjunction with the Health and Care Transformation Programme in the Cabinet Office.

The consultation aims to identify solutions to improve the health and social care complaints process and outlines an updated approach for complaints handling that is set out in supporting new Regulations. The consultation aim to meet the Tynwald motion from April 2021¹ and considers the recommendations from the Report of the Select Committee on Petition for Redress of grievance in 2006² (“**the Select Committee**”).

Following on from the establishment of Manx Care and the redesigned Department from 1 April 2021 there is now greater emphasis on transparency and planning for a modern legislative framework for the Island’s health and social care system.

The consultation aims to be open about the current situation and the steps that the Department is taking and could take in future to improve complaints handling across the health and social care system, as a result the consultation is in two parts:

Part 1 – Short term – by Regulations

The purpose of this document is to seek your views on the proposed content of several sets of draft Regulations to modernise the complaints process, including the independent review stage.

Changes to Regulations, subject to Tynwald approval, provide a short term solution to integrate the complaints process further in legislation which aims to minimise the risk of delays in reviewing complaints, inconsistent decision making and provides greater transparency of activity and learning.

Part 2 – Longer term - reform

The second consultation poses some questions that will help to shape the approach to the handling of complaints in the longer-term, as part of a comprehensive review under the Department’s National Health and Social Care Services Bill (“**the Reform Bill**”). The aim of

¹ <https://www.tynwald.org.im/business/hansard/20002020/t210421.pdf>

² <https://www.tynwald.org.im/business/pp/Reports/2006-PP-0097.pdf>

this Bill will be to modernise and consolidate the existing primary legislation in relation to the National Health and Social Care Service.

The reason for bringing in legislative change in stages is that certain changes are only possible by introducing an Act of Tynwald (primary legislation) which takes significantly longer than introducing or amending Regulations (secondary legislation). A new Act of Tynwald (the Reform Bill) will be needed to comprehensively review and modernise the complaints arrangements. The Reform Bill is currently anticipated to be introduced to Tynwald in autumn 2023 based on resource available to the Department, the Attorney General's Chambers and the Transformation Programme at present. However, efforts are being made to accelerate this work by seeking additional dedicated resource.

Part 2 of this consultation, which can be accessed here (insert link to part 2), seeks views on the Department's longer-term plans for reform of complaints handling that can only be dealt with in primary legislation (the Reform Bill). It is expected that areas for further consideration will arise from the public consultation process but, at this early stage, some of the key objectives will be to:

- set out new statutory duties and responsibilities for the organisations handling health or social care complaints on the Island,
- require the Department to set out a corporate complaints policy,
- consider whether the Department should be required to set complaints handling quality standards for service providers,
- consider whether the Department should be able to require all health and social care providers operating in the Island (including private providers) to have a statutory complaints process,
- create a truly independent adjudicator or Ombudsman for the review of all health and social care complaints, and
- enhance the ability to access to records relevant to a complaint.

Responding to the consultation

All feedback that you provide to the consultation will be valuable in ensuring that the complaints process is as effective as possible. You do not have to answer every question for your feedback to be counted and considered. You may respond to either one or both of the consultations. The deadline for responses is 18 October 2021.

Paper copies of this consultation can be requested from:

Complaints Modernisation Consultation,
Georgina Jones,
Department of Health and Social Care,
Crookall House,
Demesne Road,
Douglas,
IM1 3QA.
Telephone: +44 1624 685167

When submitting a response please bear in mind the following:

1. Any abusive or offensive responses will be discounted.
2. Please let us know the name of the organisation that you are responding on behalf of, if applicable.
3. Your response will be carefully considered; however, it does not guarantee that your proposals or preferences will ultimately form a part of the new legal framework for the complaints procedure.
4. Your response will be reviewed by officers from both the Department of Health and Social Care and the Cabinet Office as these two Departments are working together to progress this work.
5. We would welcome your response at the earliest opportunity ahead of the closing date.

Publishing responses

We will publish all responses where permission has been provided for us to do so after the consultation has closed. Therefore, information you provide to us, including your own personal data may be published or disclosed. Where this is the case, it will be done in accordance with the Island's data protection legislation.

A paper copy of the Consultation may be requested from the Department. In respect of written responses (e.g. by letter or email), if you want your response and/or personal information to remain confidential, then please clearly mark your response as confidential. An automatic confidentiality disclaimer generated by your IT system will not, in itself, be regarded as binding.

In respect of responses made via the Isle of Man Government's consultation hub at consult.gov.im, you will be asked at the beginning of the consultation to indicate if you would prefer your response to be published in full, anonymously or not at all.

Queries

If you have any queries that relate to how this consultation has been carried out, please contact Georgina Jones by e-mail at: georgina.jones@gov.im

Code of Practice on Consultation

This consultation is being carried out in accordance with the Government's Public Engagement and Consultation Principles, October 2017, which sets out eight criteria for consultations:

1. Consultations have a purpose and offer genuine opportunities to make a difference.
2. Consultations follow a clear and open process.
3. Consultations are well planned and delivered in a reasonable timescale.
4. We encourage and enable everyone affected to get involved, if they wish to.
5. We provide jargon free and understandable information.
6. Use suitable methods to deliver the consultation.
7. We learn and share lessons to improve future consultations.
8. We tell people the impact of their contribution.

Background

As a result of its establishment on 1 April 2021, Manx Care now has responsibility for the delivery of health and social care services to patients and service users, whereas the Department is responsible for oversight of the Island's health and social care system including matters of strategy, planning, finance, regulation and assurance. Each year the Department will require Manx Care to provide a range of services to a specified standard for a certain amount of funding to address the needs of the population of the Isle of Man. This is set out within a document called the [Mandate](#)³.

Health and social care complaints handling is undertaken under the National Health Service Act 2001, Social Services Act 2011, the Children and Young Persons Act 2001 and Regulations⁴ ("**Complaints Regulations**") made under those Acts. From 1 April changes were made to the Complaints Regulations and to the complaints handling procedures operated by the Department, Manx Care and the Independent Review Bodies to provide an interim solution to ensure that patients and service users are able to make representations about their care and treatment.

The current Complaints Regulations mirror NHS complaint handling arrangements in force in England until 2004, most notably the consideration by an Independent Review Body. Since 2009 in England, NHS complaints handling has consisted of a simple two stage process involving local resolution (informal and formal complaints handling) and an automatic right of access to an independent ombudsman. The main rationale for this change was that internally arranged 'independent review' mechanisms were perceived by the public as lacking impartiality, objectivity and credibility. The Isle of Man Regulations continue to reflect the historic position with the final point of adjudication for complaints resting with the Health Independent Review Body or the Social Services Independent Review Body (as applicable) and so the Regulations require a review to bring them up to date with best practice.

³ For more information on the split between the Department and Manx Care, see the quick reference guide: <https://www.gov.im/media/1372143/redesigned-dhsc-and-manx-care-quick-reference-guide.pdf>

⁴ The National Health Service (Complaints) (Amendment) Regulations 2021, the National Health Service (Independent Review Body) (Amendment) Regulations 2021, and the Social Services Independent Review Body (Amendment) Regulations 2021

Summary of Proposals

Included within this consultation are draft copies of eight sets of Regulations that are planned for introduction to Tynwald.

These are:

1. The **National Health Service (Complaints Regulations) 2021**, which set out the procedure to be followed in relation to health care complaints;
2. The **Social Services (Complaints) Regulations 2021**, which set out the procedure to be followed in relation to social care complaints;
3. The **Social Services for Children (Complaints) Regulations 2021**, which set out the procedure to be followed in relation to complaints about social care services provided to children;
4. The **Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021**, which cover the membership of the Independent Review Body and how complaints to it are to be considered;
5. The **Social Services Act 2011 (Section 26) (Amendment) Regulations 2021** to amend the Social Services Act 2011 to allow the Regulations at (2) to be made under it;
6. The **National Health Service Act 2001 (Section 38) (Amendment) Regulations 2021** to amend the National Health Services Act 2001 to allow the Regulations at (1) to be made under it;
7. The **Children and Young Persons Act 2001 (Amendment) Regulations 2021**, to amend the Children and Young Persons Act 2001 to allow the Regulations at (3) to be made under it; and
8. The **Manx Care Act 2021 (Schedule 2) (Amendment) Regulations 2021** to amend the mandate requirements under the Manx Care Act 2021 to fit with the revisions being made by these Regulations.

Additionally, there may be consequential amendments required to the complaints provisions within the National Health Service (General Ophthalmic Services) Regulations 2004 and the National Health Service (Pharmaceutical Services) Regulations 2005 which are currently being considered by the Department.

The short-term changes being sought require changes to a wide range of Regulations. The consultation is structured to assist you in understanding the principles of the proposed amendments, rather than presenting section by section amendments in detail.

There are limitations on possible amendments that can be made by Regulations and fundamental modernisation will only be achieved by the primary legislation changes as outlined in Part 2 of this consultation on which your views are also being sought.

In summary, these Regulations set out to achieve the following key objectives, on which we hope to gather feedback:

- a **complaints procedure set out within legislation for complaints made about all health and social care services offered as part of the National Health and Social Care Service** (whether these are provided by Manx Care, or other providers that Manx Care has made arrangements with to provide such services). Tynwald asked that the timescales and actions to be taken are set out in Regulations so that the processes cannot be changed easily and a consistent process is used across all services. It will also allow for a single integrated complaints policy to be created for all services provided by Manx Care;
- requiring Manx Care to:
 - provide more assistance to people that have experienced an issue and wish to raise it informally or as a complaint. This will be offered as part of an **advice and liaison service** providing confidential guidance and support to patients and service users that is already being delivered and developed by Manx Care (<https://www.gov.im/about-the-government/statutory-boards/manx-care/manx-care-advice-and-liaison-service-mcals/>); and
 - arrange for a separate **advocacy service** to be provided to assist people to make complaints;
- combining the Health Services Independent Review Body and Social Services Independent Review Body into a **single combined Independent Review Body** (“**combined IRB**”) as a short-term improvement over the current system, addressing inconsistencies between the current bodies;
- ensuring **ongoing training of the combined IRB members**;
- making changes to **time limits for independent reviews** to bring them in line with internationally recognised best practice;

- making **more information available** to the complainant at appropriate points within the complaints process; and
- requiring **people dealing with complaints to be suitably qualified, competent and experienced** in both the process and investigation.

Proposals

1. Handling and Consideration of Complaints by Service Providers (see Regulation 13 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021; and, the new paragraph 2A of Schedule 2 to the Manx Care Act 2021 set out in the Manx Care Act 2021 (Schedule 2) (Amendment) Regulations 2021)

Patients and service users should have access to advice, support and clear guidance for making complaints. In the UK, hospitals have patient **advice and liaison services** (“**PALS**”) which provide a point of contact for patients and their families and carers. This service is there to offer information, guidance and confidential advice about health-related matters, including help to resolve concerns or problems. Information and guidance can be provided by PALS officers on how to make a complaint. Requiring Manx Care to have a similar service across all health and social care services would help to make the complaints process more accessible for patients and service users. The service would also deal with concerns that can be resolved easily to stop them escalating into complaints. Manx Care have already launched this service, additional information can be found here: <https://www.gov.im/about-the-government/statutory-boards/manx-care/manx-care-advice-and-liaison-service-mcals/>.

One thing that MCALS would not do is provide direct support to complainants during the process of making a complaint. However, another proposal is to require an **independent advocacy** service to be facilitated by Manx Care to assist service users with the complaints procedure.

Advocacy means giving a person support to have their voice heard. It is a service aimed at helping people understand their rights and express their views. For example, service users would be able to ask someone from the advocacy service to attend a meeting with them, to assist in writing a complaint letter or to help accessing and reviewing information given during the complaints process.

This service would not be intended to replace other advocacy services already available on the Island such as the Health and Care Association, Age Concern and United Response or that already in place for mental health services. The aim is to ensure that every service user has access to an advocacy service if needed.

It is also proposed that the Department should have a role in offering advice and guidance across the *whole* Health and Social Care Service. The proposal is for a statutory requirement

for the **Department to provide advice and guidance to the public**, both face to face and in writing, about the way in which they can make a complaint and to direct people to relevant support available, such as pointing people in the direction of Manx Care's advice and liaison service, the independent advocacy services or a provider's own complaints process in the early stage of seeking resolution.

Questions

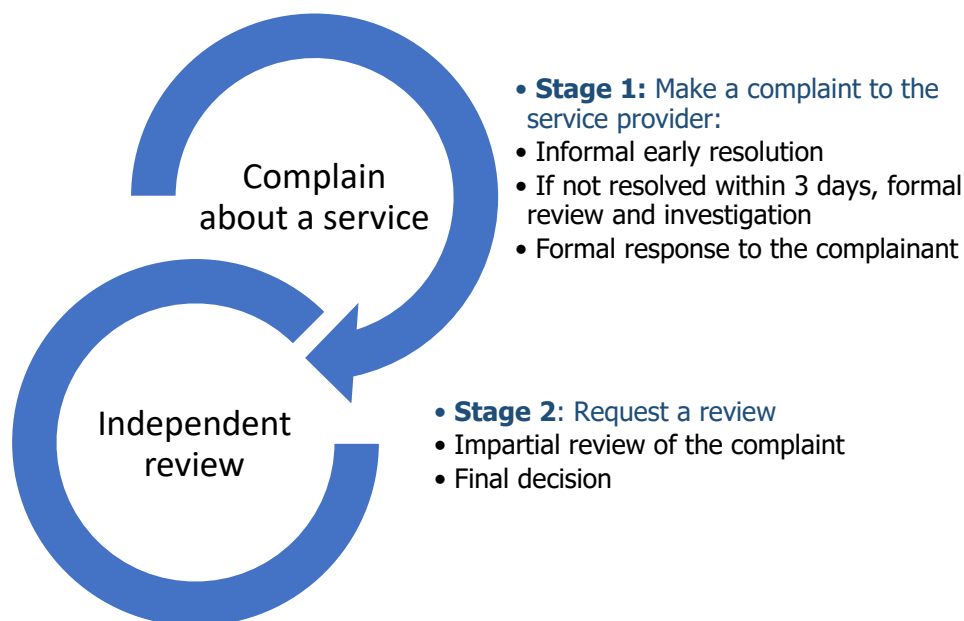
Manx Care's Advice and Liaison service will be accessible for persons using any NHS or social care service (e.g. adult residential care, learning and disabilities services provided by Manx Care).

- 1.1 Do you have any comments on the scope of the Manx Care Advice and Liaison Service?
- 1.2 If you had an issue with a Manx Care health or social care service that you had received, what would you expect from Manx Care Advice and Liaison Service?
- 1.3. What services should the Manx Care independent advocacy service provide?
- 1.4. Do you support the obligation for the Department to be required to provide advice and guidance about how to make a complaint and about any support available?
- 1.5. What do you think are the best ways to provide advice, information and guidance to service users?

2. A simpler process for making complaints (set out in Part 2 and regulations 28 and 29 of the National Health Services (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 the Social Services for Children (Complaints) Regulations 2021)

It is intended that there should be an easy to follow and accessible **two stage process** for a member of the public who wishes to make a complaint about any health or social care service received (from Manx Care or another provider) under the mandate from the Department, as follows:

1. **Complain to the provider of the service** (which is known as local resolution)
2. **Request a review by an independent adjudicator** (if not satisfied with the outcome of stage 1 or if stage 1 has not been completed within 6 months).



The above diagram illustrates this two stage process and the key steps involved within each stage. Annex 1 contains a more detailed flow to demonstrate the complainant’s journey on the proposed two stage process for complaints.

At **stage 1** issues that are raised orally with a staff member and resolved within three working days do not need to be considered as complaints. All other issues will be dealt with as complaints and so will be subject to a formal review and investigation process by the service provider and will result in a written response to the complainant.

Stage 2 of the process is used where the complainant is not satisfied with the outcome of the local resolution stage (either the resolution offered or if the service provider declines to investigate because the complaint had not been made within the 12 month time limit) or if the local resolution process has not been completed within 6 months of the complaint being made. At this stage, the complaint can be submitted to the combined IRB for a review. The combined IRB’s role is to resolve cases, where, after the service provider has given a considered view, differences still remain between the organisation and the complainant.

The proposed two stage process is aligned with the best practice principles of the [Ombudsman Association](#) (a professional association for ombudsman schemes and complaint handlers in the UK, Ireland, British Overseas Territories and British Crown Dependencies), which sets out that a complaints process should have one independent adjudicator to be the final neutral port of call in relation to a dispute.

However, it is important to note that the Mental Health Commission has a legal obligation under the Mental Health Act 1998 to investigate any complaint made to it by a patient detained under the Act (section 118(1)(b)). This statutory requirement will continue to be accommodated within the complaints process and will not be affected by the proposed amendments to the complaints Regulations. The Department considers this to be an interim position as further consideration will be given to this function within the longer term changes to be made as a result of the Reform Bill.

It is proposed that organisations that provide health or social care services under arrangements made with Manx Care (or transferred from the Department to Manx Care in April 2021) will be required to comply with the Regulations setting out the process for making complaints within 6 months of the Regulations coming into operation or when the contract is renewed, whichever happens soonest. The statutory complaints arrangements will be new for many of these organisations and so this transition period will give those organisations time to put in place arrangements that are compliant or to renegotiate the contract, if necessary. Manx Care will be required to comply with the Regulations from the time that they come into operation.

Question

2.1 Do you have any comments on the proposed two stage process for complaints?

2.2 Do you have any comments on the proposed transition period for providers of health and social care services other than Manx Care?

3. Making a complaint about a service (set out in Part 2 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

The current Regulations set out that complaints regarding health services must be made by patients within 6 months of the complainant becoming aware of the matter. The new Regulations will apply to both health and social care services and the timescale for making a complaint is being reviewed. It is proposed that the timescale should be extended so it is in line with internationally recognised best practice, which would allow complaints to be made at any time within 12 months of the person becoming aware of the matter that they wish to complain about.

It is also proposed that the current prescribed timescale for acknowledging a complaint should be increased from 2 working days to 5 working days in line with the process in England, which is thought to be a more realistic target for a 24 hour, 7 day a week service. This will allow time for some additional information to be provided in the acknowledgement letter, if the complaint has not been resolved at the time of the acknowledgement, as follows:

- a summary of the complaint,
- details of the complaints handling procedures,
- the anticipated time for when the complainant should expect a further response,
- details for a point of contact for the complainant to deal with, and
- a request for further details or clarification from the complainant as required.

Question

3.1. Do you have any comments on the proposed changes to be made in relation to making a complaint and it being acknowledged?

4. People dealing with complaints (see regulations 5, 11 and 16 of the draft National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

During the debate on the April 2021 motion, Tynwald noted that people dealing with complaints need to be experienced in doing so.

“People dealing with complaints” extends beyond people working directly within the complaints process (such as administration staff or persons conducting clinical safety and quality investigations) and could capture everyone that is involved in providing health and social services to the public. Most health and social care organisations should have specified roles and responsibilities for staff in relation to complaints. It is necessary to ensure there is relevant and proportionate complaints training and communications that meets this requirement.

The current Complaints Regulations require service providers to have a ‘complaints manager’ function, (which may not necessarily be a dedicated role, but form part of an overall managerial role). The purpose of this function is to ensure there is a dedicated individual who

has responsibility for managing the organisation's complaints procedures. The revised Regulations will retain this role but will be supplemented with:

- a requirement that the service provider has to make sure that the '**complaints manager**' has adequate and appropriate expertise, resources and authority to carry out its activities effectively;
- an additional role of '**responsible officer**' that must ensure compliance with the arrangements made for handling complaints, particularly in relation to action being taken and learning resulting from complaints and must sign the response letters from the service provider; and
- a requirement that '**all staff**' are appropriately trained and supported to deal with complaints.

Question

4.1. Do you have any views on the suggestions to ensure that people dealing with complaints are experienced in doing so?

5. Investigating the complaint and keeping the complainant informed (see regulations 4, 8 and 11 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

Improvements to how the investigation must be carried out by the service provider are proposed within the new draft Regulations. The current requirements for the service provider to:

- investigate the complaint speedily and efficiently; and
- ensure that appropriate mediation services are available and are given power to make arrangements with the complainant for mediation or for other assistance to be provided for the purpose of resolving the complaint;

will be **supplemented with requirements to:**

- ensure that complaints are welcomed in a positive way;
- ensure that complainants are given fair and accountable responses;
- ensure that complaints are investigated thoroughly and fairly;

- ensure that a just a learning culture is promoted;
- invite the complainant to attend a meeting to discuss the complaint and offer an opportunity to meet with a relevant health or social care professional who can answer any questions about the specifics of the complaint. The complainant can be accompanied at either of the meetings or the meeting could be attended by someone acting on the complainant’s behalf in relation to the complaint; and
- take steps to keep the complainant informed about the progress of the investigation on a regular basis (and at least at 20 working days after the submission of the complaint).

A **specific exclusion** is included within the current Regulations that prevents a complaint from being investigated where the complainant has stated in writing that they intend to take legal proceedings. The default position in England since 2009 is that where a complainant expresses an intention to take legal proceedings, an NHS body should continue to try to resolve the complaint quickly unless there are compelling legal reasons not to do so. It is intended that this should be the case on the Island and so, in cases where the complainant is taking or plans to take, legal proceedings, a complaint may only be put on hold by a service provider where there are exceptional reasons to justify it, or the complainant has requested that investigation be delayed. Exceptional circumstances for putting a complaint on hold would include formal requests to do so (for example by the police, a coroner or a judge).

Questions

5.1 Do you agree with the additional requirements?

5.2 If you disagree, or have additional suggestions, please provide further comment.

5.3 Do you agree that complaints should continue to be investigated properly and responded to if the complaint is also planning to take legal action?

5.4 If you disagree, please provide further comment.

6. Formal response to the complainant (set out in Part 2 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

The Regulations currently require a formal response to be sent to the complainant within 20 working days of the complaint being made. This is a short timescale when compared to the requirement in England, which is 6 months, and when considered in the context of the complexity of some of the complaints received.

However, it is proposed that the **20 working day standard response time is retained**. This timeframe is appropriate for straightforward complaints which can, and should, be resolved quickly. However, for more complex complaints where the investigation takes longer than 20 working days, a new requirement has been added so that where the formal response has not been sent to the complainant by the 20th working day, the service provider must **notify the complainant of the reason for the delay and advise the complainant of a revised timescale** for when he or she can expect to receive a response.

It is acknowledged that more complex complaints will take longer than 20 days to investigate. In such cases, regular updates should be provided to the complainant to keep them informed of progress. The investigation should be thorough and fair to give an open and honest answer as quickly as possible in light of the complexity of the issues raised. It is best practice for the service provider to try to resolve the complaint at this local resolution stage which may need further dialogue and action in order to satisfy the complainant.

Under the proposals, the service provider will also be required to ensure that any remedial action to be taken to resolve the complaint or any **action taken to address learning from the complaint is taken promptly**. It is not considered that a meaningful standard timescale for this action to be taken can be set within Regulations. This is because the range of actions that could result from complaints will be so variable. The service provider should provide a fair and accountable response to the complainant that covers what happened and whether mistakes occurred and will be required to set out **a reasonable timescale for any remedial action to be completed**.

The requirement for the response to notify the complainant of his or her right to refer the complaint to the Independent Review Body will be retained and it will be a requirement that the **contact details for the Independent Review Body must be provided** in that correspondence.

Questions

6.1 Do you agree that 20 days should be the normal statutory response time for complaints?

6.2 If you disagree, please provide further comment.

7. Requesting a review from an independent body (set out in Part 3 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

The complainant may request that the complaint is reviewed by an independent body if:

- he or she is not satisfied with the response received under the local resolution arrangements;
- the investigation of the complaint at local resolution has not been completed within 6 months; or
- if the complaint was not investigated at local resolution level because it was not submitted within the 12 month time limit for making complaints but the complainant feels that he or she had good reasons for not making the complaint within the time limit and that it would still be possible for the service provider to investigate the complaint.

Currently, complaints relating to health services are reviewed by the Health Services Independent Review Body and complaints relating to social services can be reviewed by the Social Services Independent Review Body. Additionally, complaints relating to the exercise of powers under the Mental Health Act 1998 may be reviewed by the Mental Health Commission.

This means that there are inconsistencies between how complaints are dealt with depending on which service it relates to and access to an independent review may be unnecessarily confusing for the complainant. As requested by Tynwald, the Department now aims to move towards a single independent review of complaints function relating to health *and* social care services.

To achieve this, an integrated Independent Review Body (the combined IRB (called the Health and Social Services Independent Review Body within the Regulations)) will be established. As previously stated, the Mental Health Commission will continue to have a remit to review complaints under the Mental Health Act 1998.

In the longer-term, the Department wishes to consider having a completely independent adjudicator for reviewing all health and social care complaints, the options for this are set out

in Part 2 of the consultation. However, this cannot be achieved in law in the short term and so the combined IRB should be viewed as an improved, interim position as part of this journey.

The following sections set out more detailed considerations about the proposed combined IRB.

8. Who will be members of the combined IRB? (see the Social Services Act 2001 (Amendment) Regulations 2021 new section 26A and regulations 4 and 5 of the Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021)

It is proposed that the combined IRB will be made up of nine members (on the basis that currently there are 6 members on the Health Services IRB and 3 on the Social Services IRB) that have relevant experience as the Appointments Commission⁵ considers appropriate, such as in health, social care, dispute resolution or administrative justice. At least one of the members will be required to have a recognised qualification in health care and at least one of the members will be required to have a recognised qualification in social care.

Consideration is being given to whether some of the combined IRB members could be from outside the Island which may increase the independence and the pool from which members could be sought. Members would need to be available to meet with a complainant and could do this virtually or by arranging to visit the Island for meetings and meet with complaints.

It is proposed that the combined IRB will be newly formed with members appointed by the Appointments Commission, which has the following benefits:

- is an acknowledged independent body set up in law to make appointments in accordance with relevant legislation;
- it is experienced in independent recruitment to statutory bodies; and
- it has a systematic and consistent approach to appointing to independent bodies across all sectors across government.

It is proposed that the combined IRB will be funded by the Department and will have the support of a secretariat function appointed by the Public Services Commission and funded by

⁵ The Appointments Commission is an independent body established by the Council of Ministers whose function is to make appointments to various Tribunals and other bodies.

the Department. This is considered to be an appropriate level of independence for the combined IRB in the short term because from 1 April 2021 the Department no longer provides any health or social care services and so the combined IRB will not be reviewing complaints about the Department. There is a remote possibility that the Department is required to provide or arrange for services to be provided in future as a last resort, if Manx Care was failing to do so, which is why other independent complaint review options are considered in Part 2 of this consultation.

The Department considers that initial and ongoing training for members and the secretary is essential. It is proposed that the combined IRB will set out a training plan for members on an annual basis that must be agreed and funded by the Department.

Questions

- 8.1. What are your views about the proposed membership of the combined IRB?
- 8.2. What are your views about the proposed requirements in respect of experience, qualifications and training of members?
- 8.3. Do you think that any ongoing training requirements should be set out within the Regulations?
- 8.4. Please provide reasons for your response to question 8.3.

9. What will the combined IRB's role be? (see regulations 18 and 20 of the National Health Service (Complaints) Regulations, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

The combined IRB would review complaints relating to all health and social care services that have already been investigated by the organisation that provided the service but have not been resolved to the complainant's satisfaction. The combined IRB's role is to look at complaints fairly and without taking sides in order to reach a resolution.

The combined IRB could also review the organisation's actions in relation to complaints where the final response has not been issued within 6 months of the complaint being made or where the organisation that provided the service has declined to review the complaint because it has not been made to it within the 12 month time.

The time limit for making a complaint to the combined IRB is proposed to be within 1 year after the date on which the complainant became aware of the problem. This is extended from the current 28 days after the date of the service provider's decision about the complaint. There is also flexibility provided, at the discretion of the combined IRB Chairperson, in respect of this timeframe.

This new time limit would generally provide patients and service users with longer to request a review, which is important given that the person may be experiencing difficulties, emotional distress or be suffering with a condition that could take many months to recover from and so capacity to make a complaint about something that took place earlier in their treatment may not be regained for some time. The extended timeframe is in line with the time limits for requesting an independent review in the UK by the Parliamentary and Health Services Ombudsman or the Local Government and Social Care Ombudsman.

Question

9.1. Do you have any comments on the remit and time limit for making a complaint to the combined IRB?

10. Making a complaint to the combined IRB (set out in Part 3 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

A requirement is included within the draft Regulations for the combined IRB to give **effective publicity to its complaints arrangements**, which would mean that a webpage with a telephone number and a leaflet for complainants (at least) would be required to help people know how to request a review of a complaint.

Requests for reviews into complaints should be **submitted on a standard form** and the draft Regulations propose to make this a requirement.

When the combined IRB has received the complaint, they will do some **initial checks** to make sure they can deal with it. This includes checking that;

- it has been submitted on the standard form,

- the combined IRB can look into the organisation and issue that has been complained about, and
- the complainant has been through the organisation's complaints process.

This initial check should be completed within 5 working days, after which an acknowledgement will be sent to the complainant.

The next step is to take a closer look at the complaint to decide **if the combined IRB should review the complaint**. During this time **a meeting will be offered to the complainant** in order to hear more about the complaint and a high level review will be carried out against some standard considerations, which will be listed within the Regulations. This will mean that the combined IRB will look at the following things:

- whether the complainant has been affected directly by what happened;
- whether the organisation that is being complained about has reached a resolution with the complainant that is fair and reasonable in the circumstances;
- whether the complaint has been made within the 12 month time limit;
- whether the complainant has taken legal action that has been decided upon by a court;
- whether the complainant has (or had) the option of appeal, reference or review to a tribunal constituted by or under any enactment (such as the Mental Health Review Tribunal);
- whether the complaint has been considered under another law that sets out a process for the resolution of disputes or the investigation of complaints (such as complaints referred to the Mental Health Commission under the Mental Health Act 1998); or
- whether it would be better for the complaint to be dealt with by a court or by a different process set out in law (as set out above).

The combined IRB will make a decision on whether or not they can review the complaint and then let the complainant, the organisation that is the subject of the complaint and the Department know. If the combined IRB cannot review the complaint, they will be required to explain why and set out what other options might be open to the complainant.

The Health Services IRB and Social Services IRB are currently required to notify the complainant of their decision in relation to whether or not they will consider the complaint as soon as reasonably practicable. The draft Regulations propose that this should be changed to bring in a definite deadline of 20 working days in line with the standards for the Parliamentary and Health Services Ombudsman in England. However, if the meeting

with the complainant has not been able to be arranged within the 20 working days, this timeframe can be extended to ensure that the combined IRB has the necessary information to consider whether or not it can review the complaint.

Question

10.1 Do you have any comments on the proposed process or standard considerations for the initial review?

11. Reviewing the complaint (set out in Part 3 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

If the combined IRB can review the complaint, they will gather all of the information needed from the complainant and the service provider. It is proposed that the service provider will be required within the Regulations to provide the information requested of it in good order and **within 6 weeks** from when the request is made. If the service provider cannot comply with this standard response time, they will be required to explain why and agree another reasonable timescale with the combined IRB. This new requirement is to avoid the possibility of disorganised or illegible documentation being provided, which would impact on the ability of the combined IRB to meet its response timescales.

In terms of data protection, the combined IRB will be required to obtain the complainant's consent to receive the necessary personal data from the service provider. In the case of a person who is deceased, the combined IRB will have power to request the records that it requires if it can demonstrate to the service provider that it has the consent of a valid personal representative of the deceased. This is different to the current rights of access that the personal representative has to the data, which are more limited since the current primary legislation only allows for personal representatives to access a deceased person's health records, but does not allow access to their social care records. There may also be difficulties for the service user in navigating the legislation if they personally want to access the records of a deceased person. This issue is discussed further in part 2 of the consultation as a long-term consideration for change to the primary legislation.

The combined IRB may also convene a hearing to take oral evidence or advice in relation to the complaint. The Regulations provide a right for any person who is giving evidence before the hearing to be accompanied whereas presently, only complainants have that right.

Once the information has been received, the combined IRB will consider the handling of the complaint by the service provider against the relevant Complaints Regulations and decide whether the service provider's response was reasonable and appropriate in light of the findings, conclusions and recommendations of their investigation into the complaint. Where necessary, independent expert advice will be sought in relation to the subject matter of the complaint. Following the review, the combined IRB can decide to uphold a complaint, reject a complaint or refer the matter back to the organisation that provided the service for further action. The combined IRB will issue a report that summarises its findings and recommendations for action to be taken to resolve the complaint.

Question

11.1. Do you have any views on the proposed process set out for the combined IRB's review of a complaint?

12. Final decision (set out in Part 3 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

The current Regulations require the Social Services Independent Review Body to prepare a written report of its investigation within 28 days of a complaint being made whilst the Health Services Independent Review Body does not have a prescribed timescale. The proposal is for the written report containing the combined IRB's final decision to be sent to the complainant within 6 months of the complaint being received, which would bring this timescale in line with both the Parliamentary and Health Services Ombudsman and the Local Government and Social Care Ombudsman in the UK. A new requirement in the draft Regulations would ensure that the combined IRB must publish a copy of each report into a complaint investigation (redacted so that it does not contain any personal data).

If the complaint is upheld, it means that the organisation got things wrong and the complainant has been negatively affected because of this. It also means things haven't been put right and the combined IRB will recommend what the organisation should do about this.

The combined IRB's decision will be final and there will be no recourse for appealing against that decision. This mirrors the situation in England.

However, there is a new requirement for the combined IRB to put in place and operate an internal complaints procedure about the way that it has handled the complaint review. This requirement is only in relation to the process that has been followed in considering the complaint and will not be a mechanism through which complainants can appeal the decision made by the combined IRB. The combined IRB will be required to report annually to the Department on the number of complaints that it has received about its operation and any improvements it has made to its processes as a result of those complaints. The combined IRB's annual report will be required to be laid before Tynwald by the Department.

Question

12.1. Do you have any comments about the combined IRB having the final decision on a complaint referred to it?

12.2. Do you think that there should be a mechanism for a further review of how the combined IRB has handled a complaint, such as a review by the Department or the Tynwald Commissioner for Administration?

12.3. If yes, who do you think should fulfil that role and what value do you believe that review would add?

13. Learning from complaints (see regulation 12 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

A new requirement for the service provider to **demonstrate that it is learning from the complaints** it receives has been included within the Regulations. Whilst this consultation focusses on the legislative changes to be made, it is acknowledged that this requirement will need to be brought in alongside behavioural change leading to an improved learning and just culture, in which complaints are welcomed and handled well.

Specific actions are required within the Regulations:

- systems must be in place to **record, analyse and report on learning** from complaints;
- appropriate mechanisms must be in place for complainants to **share feedback** about their experience of the complaint handling process;
- referral to a health or social care regulatory body must be considered and acted upon where a complaint indicates non-compliance with a Code of Conduct or other professional requirement or expectation set by those bodies;
- **learning from complaints must take place to prevent the same mistakes happening again or to improve services**, and
- reviews of complaints against duty of candour incidents must be carried out on a quarterly basis to establish links with reported and unreported duty of candour incidents and action must be taken to rectify any issues in applying the duty of candour procedure highlighted by the review. Duty of candour incidents are incidents where unexpected or unintended harm, as defined within the Manx Care (Duty of Candour Procedure) Regulations 2021, has resulted from a service provision to a service user. Whilst not every complaint will relate to a duty of candour incident and not every duty of candour incident will result in a complaint by the service user, there are sometimes cross overs between the two procedures.

Question

13. 1 Do you have any views about the new regulation (12) to address learning from complaints?

14. Transparency, accountability and assurance (see regulations 14, 15, 24, 25 and 26 of the National Health Service (Complaints) Regulations 2021, the Social Services (Complaints) Regulations 2021 and the Social Services for Children (Complaints) Regulations 2021)

The Department, Manx Care and the combined IRB will be held to account through public reporting requirements included within the draft Regulations as well as through existing requirements for inspections of service providers that are carried out by the Registration and Inspections Team of the Department ("**RIU**") and the external inspectors appointed under the Manx Care Act 2021 to inspect services provided on behalf of the Department.

Inspection reports following the independent inspections carried out under the Manx Care Act 2021 will be made public along with Manx Care's action plan for addressing the shortcomings. The Department will hold Manx Care to account in implementing the published action plan.

Inspection reports following RIU inspections are made public. RIU will consider enforcement action where there are significant breaches of the minimum standards.

The combined IRB will be able to make 'discretionary recommendations', meaning that the service provider can decide whether or not to act on the recommendations given. This is an established principle accepted by the Ombudsman Association. Giving the combined IRB a mandatory power of enforcement could result in legal challenges. However, it is proposed that the **Department will hold Manx Care to account in implementing the accepted recommendations made by the combined IRB.**

The Department will be held to account for its responsibilities in relation to complaints through its annual reporting to Tynwald, Tynwald Scrutiny Committees and the Tynwald Auditor General. It will be required to prepare an **annual report in relation to complaints handling within 6 months of the financial year end and lay it before Tynwald** – this is in line with the timescale for the annual reporting requirement for the Department in the Manx Care Act 2021 – the Department will use information from the reports provided by Manx Care and the combined IRB to inform its own complaints handling report.

As part of the Department's role to oversee the quality and safety of services provided under the mandate, it will request information from Manx Care in order to hold Manx Care to account in the way in which it handles complaints. Under the Regulations, **Manx Care will be required to report annually to the Department** within 3 months of the end of each financial year. It is proposed that the report will include details of:

- the number of complaints in relation to services provided under the mandate,
- what subject matter the complaints related to,
- a summary of how these were handled including the outcome,
- a statement on any changes or improvements being made as a result,
- the time taken to respond, and
- any complaints where recommendations of the combined IRB were not acted upon and the reasons why not.

In order to fulfil this reporting requirement, and as part of Manx Care’s contractual arrangements with other providers of health and social care services, Manx Care will require regular reporting from its contracted providers in relation to their complaints handling over that period.

The Regulations will require the **combined IRB to report to the Department on an annual basis and for that report to be submitted to Tynwald** (to the sitting after the report is prepared). It is proposed that the report should contain:

- the time taken to investigate complaints, including how many have taken longer than 6 months to investigate,
- the actions being taken to ensure that all investigations are concluded within 12 months,
- an anonymised summary of complaints concluded during the financial year,
- a report on all outstanding recommendations made by the combined IRB, and
- information about any complaints made about the combined IRB.

The Department will be required to publish the report it receives from the combined IRB on its website.

The Department does not consider that creating offences or monetary fines for breach of the complaints regulations is an appropriate way to hold service providers to account in complying with this legislation. Creating penalties in the form of fines runs the risk of taking money away from service providers that would otherwise be spent on the provision of services and so ultimately creating more harm than good for service users. The Regulations will instead be brought in as part of developing a learning culture within the organisations providing the services.

Question

14.1. Do you have any comments about the type of information that you would want to see in the annual reporting from the Department, Manx Care or the combined IRB?

14. 2. Would you expect to see annual reports on outcomes and learning from complaints published by each health and social care service provider as well as Manx Care and the Department?

15. Equal opportunities

An initial assessment of the complaints arrangements set out within the Complaints Regulations has shown that communications made to patients and service users would need to be tailored appropriately in order to ensure that everyone is given the same opportunity to receive, digest and question the information shared with them as part of the complaints arrangements (for example, providing information in alternative formats, such as large font, Braille or audio CDs, in easy read formats or in a different language). Additionally, the requirement for an independent advocacy service being proposed in this paper should be invaluable in ensuring that those who require it are given sufficient support and the opportunity to be accompanied and represented throughout the complaints process.

Necessary adjustments will also need to be made for people to attend meetings, such as being flexible in respect to the location of the meeting or providing transport to the meeting.

Question

15.1. Are there any other areas where this policy has the potential to adversely affect equality of opportunity?

16. Any other comments

Question

16.1. Do you have any other feedback or information that you wish to share with us as part of this consultation?

Please note that this information will be published as part of your consultation response, depending on the disclosure option that you selected at the start of this consultation.

