Isle of Man Government
Reiltys Ellan Vannin

Department of Health and Social Care

Rheynn Slaynt as Kiarail y Theay

Summary of Consultation Responses on:

Complaints Modernisation

April 2022

Delivering Longer Healthier Lives

HEALTH AND SOCIAL CARE IN THE ISLE OF MAN 2016 - 2021 5 YEARS. 5 GOALS.

CARE committed appreciative respectful excellent

Summary of consultation responses

We asked

The purpose of the consultation was to seek the views of the public and the relevant professional persons and bodies regarding the Department of Health and Social Care's ("**the Department**") proposals for:

- short term changes to the process for dealing with complaints about health and social care services (to be made by Regulations) – this was Part 1 of the consultation; and
- longer term changes to be made under the Reform Bill – this was Part 2 of the consultation.

You said

Fifty-four responses were received to Part 1 of the consultation via the online consultation hub and 8 substantial separate written responses were also received.

In relation to Part 2 of the consultation, 12 responses were received via the consultation hub and 2 separate written responses were also received.

We did

The results to Part 1 of the consultation have been analysed and the written submissions have been reviewed by the Department to inform the content of the Complaints Regulations.

In November 2021 the Department reviewed the approach to determine whether the proposed Regulations were the best way to make the changes or whether a bespoke Bill (primary legislation) could be developed to address all issues in one go.

The Department determined that it remained committed to the Tynwald resolution to complete the modernisation of the existing Regulations as far as these Regulations would permit, noting that there would be plans for further reform within the Reform Bill. This would ensure that the necessary changes were made as soon as possible.

The Department also considered the practicality of setting up a new Independent Review Body ("**IRB**") for an interim period, and decided that it would be of greater benefit to the public to move towards setting up an Ombudsman at the earliest opportunity.

Following review of the consultation responses, the Department's preference would be for an Independent Ombudsman to be set up operationally independent from the Department and Manx Care. However, it is not possible to set up such a body under the Regulations; therefore, as an interim solution, it is intended that a Health and Social Care Ombudsman Body will be set up under the Social Services Act 2011.

In March 2022, the Department learned that it did not have the power within the current Acts to make the Regulations that had been drafted and consulted upon. As a result of this, a short Bill has been drafted to amend the Manx Care Act 2021 to give the Department the necessary powers to make the Regulations that had been drafted. It is intended that this Bill will be progressed quickly through the branches of Tynwald in order that the Regulations can be laid before Tynwald in June and July as planned.

After considering the outcomes of this consultation, the Department will draft a Bill and make 8 sets of Regulations to implement the proposals.

Summary of consultation responses

Work remains outstanding to consider the responses to part 2 of the consultation and develop the additional areas outlined in that consultation including establishing an independent Ombudsman. These will be developed as part of the policy development for the Reform Bill. A public consultation on a draft Reform Bill will take place in due course.

This consultation response report is published online at: https://consult.gov.im/we_asked_you_said/

Summary of consultation responses

Contents

1. Background

Following 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 an agreed level of funding to address the needs of the population of the Isle of Man. This is set out within a document called the Mandate.

Health and social care complaints handling is currently undertaken under the National Health Service Act 2001, Social Services Act 2011, the Children and Young Persons Act 2001 and Regulations ("**Complaints Regulations**") made under those Acts. From 1 April 2021 changes were made to the Complaints Regulations and to the complaints handling procedures operated by the Department, Manx Care and the IRBs to provide an interim solution to ensure that patients and service users were able to make complaints about their care and treatment provided by Manx Care.

Since May 2021, the Department has been progressing 8 sets of Regulations to update the arrangements for dealing with complaints about health and social care services.

This work came about following the April 2021 sitting of Tynwald where Mr Shimmins tabled a motion that was unanimously accepted as follows:

That Tynwald is of the opinion that the Department of Health and Social Care (DHSC) complaints process is long overdue an overhaul and recognises that this is a departmental priority; recognises the need for an effective complaints process for both DHSC and Manx Care; notes that effective processes for complaints, whistleblowing, raising concerns and duty of candour rely on an open and transparent process for communicating between all stakeholders; believes that the revised complaints regulations, following public consultation, should be brought to Tynwald for approval by November 2021;asks the Department to restructure the Independent Review Bodies (IRB) to provide for one body to cover both health and care, and in so doing to review the IRB procedures.

The Regulations being progressed consist of 3 sets of Regulations to amend the vires in the National Health Services Act 2001, Social Services Act 2011 and the Children and Young Persons Act 2001 to allow more sets of Regulations to be made under these Acts, which will set out a statutory complaints procedure for all health and social care services offered as part of the National Health and Social Care Service on the Island.

A combined health and social services independent review mechanism in the form of an Ombudsman body is also to be regulated for.

A further set of Regulations is necessary to update the Manx Care Act 2021 to amend the process for complaints handling set out within that Act.

2. Summary of the content of the report

This consultation report provides:

- a record of the comments and feedback provided during the pre-consultation engagement on policy development for the Regulations and consultation that was undertaken with key stakeholders between 25 May and 4 June 2021;
- a record of comments and feedback provided during the Part 1 of the consultation which was promoted online between September and October 2021 with the Department's responses; and
- a record of comments and feedback provided during Part 2 of the consultation, which was promoted online between September and October 2021. The responses to Part 2 of the consultation have not yet been considered in detail, except for those in relation to the setup of an independent Ombudsman. These will be considered for inclusion within the Reform Bill.

3. Report Format

This report aims to give a complete record of the consultation process.

A summary of all responses and themes to the questions raised within Part 1 of the consultation is presented in Appendix 1.

The detailed responses received to each question within Part 1 of the consultation on the consultation hub are contained within Appendix 2.

The written responses submitted in respect of Part 1 of the consultation are contained within Appendix 3.

The detailed responses received to each question within Part 2 of the consultation on the consultation hub are contained within Appendix 4.

The responses to the pre-consultation stakeholder engagement are contain in Appendix 5.

4. Conclusions

The Department has sought the views of the public on the proposals within the updated complaints Regulations and is now in the position to tell people the impact of their contribution, by publishing feedback and a summary of responses on the Government's Consultations webpage. The summary of responses to the consultation explains how the responses have been used to make decisions and inform the content of the Regulations.

The overriding objective is to introduce updated Regulations to make improvements to the arrangements to handling complaints about health and social care services. Changes have been proposed to the process to be followed by those that have provided health or social care services (known as local resolution) as well as a newly formed Ombudsman body to provide an independent review of unresolved complaints.

It is essential that the arrangements for handling complaints are underpinned with a modern and clear legal framework. The Manx Care (Amendment) Bill 2022 ("**the Bill**") and underlying Regulations will provide this framework.

A total of 76 responses were received to Parts 1 and 2 of the Complaints Modernisation consultation. Overall, there was support for the changes being proposed.

The Department would like to express their appreciation to those that took the time to compete this consultation. The Department has responded to comments within the 'We will' mechanism in the report to provide assurances on what action will likely be progressed in light of the consultation responses provided.

Each response submitted has been considered and reported on with as much detail as possible.

If you have responded to the consultation and feel that your comment or concern has not been addressed, please contact us in the following way:

Email: dhscconsultation@gov.im Telephone: 642608

Address: Department of Health and Social Care, 1st Floor Belgravia House, Circular Road, Douglas, Isle of Man. IM1 1AE

5. Next Steps

The Regulations are being amended to take account of the changes made as a result of the consultation comments.

Subject to the Bill being progressed through Tynwald and receiving Royal Assent in the necessary timeframe, it is intended that the Regulations are published on Tynwald's register of business in May 2022 with the first set of Regulations laid Tynwald for approval in June and the second set of Regulations laid before or approved by Tynwald in July.

It is intended that the Bill will go for first reading in the House of Keys in May 2022.

Once these Regulations have been implemented, the Department will move straight onto considering the comments received to Part 2. This will inform the content of the complaints section of the Reform Bill and will include improvements to the proposed Ombudsman to make it a fully independent body able to act at an arm's length to Government. The Department intends to conduct during a public consultation on the Reform Bill itself during 2023.

Appendix 1

Complaints Modernisation Part 1 – Summary of Consultation Hub Responses

1. What is your Name?

There were 48 responses to this part of the question. Six respondents opted to respond anonymously.

2. What is your email?

There were 45 responses to this part of the question.

3. May we publish your response?

Table 3.1: There were 54 responses to this question.

Option	Total	Percent
Yes, you can publish my response in full	10	18.5%
Yes, you may publish my response anonymously	32	59.3%
No, please do not publish my response	12	22.2%
Not Answered	0	0.0%

4. Which of the following are you responding as:

Table 4.1 There were 54 responses to this question.

Option	Total	Percent
Member of the Public	42	77.8%
Works for a service provider but is responding in a personal capacity	10	18.5%
Responding on behalf of a service provider (in which case please provide organisation's name)	1	1.9%
Other	1	1.9%
Not Answered	0	0.0%

5. If you are completing the survey on behalf of an Organisation or group, please provide the name of the organisation (or group):

There were 16 responses to this question, but the only response submitted on behalf of an organisation was from Graih.

6. Handling and consideration of complaints by service providers

Whilst reviewing the responses to this question, it was noted that several respondents were not clear on the current role of Manx Care Advice and Liaison Service ("MCALS") and that there was some confusion between the role of MCALS and the role of independent advocacy. Therefore, the Department has provided further clarification below:

MCALS is a confidential help and advice service run by Manx Care that aims to improve patient and service user experiences by helping to sort problems out quickly, providing advice and pointing people in the right direction to get the help they need.

MCALS aims to respond to queries on the same day or at least within 7 days. The staff of MCALS will approach the right care team to get a response for the member of the public and would work between the individual and the care team to figure out the best way forward in relation to the issue raised. Signposting is a very important aspect of MCALS as well as accessibility and access to information concerning services.

MCALS does not deal with formal complaints but they would listen to issues raised and contact the relevant department to help address concerns initially. They will provide guidance and can advise people on how to make a formal complaint or request their records.

It was initially set up as a trial service after which the data from the service will be reviewed and Manx Care will decide how the service should continue to operate in the future. Part of the proposals within the Regulations put MCALs onto a statutory footing so that it is a service that must continue to be operated by Manx Care in future.

Independent Advocacy services help vulnerable people to be involved in the decisions that affect their lives. An independent advocate should represent a person's wishes without judging or giving a personal opinion. They can do this on the person's behalf or can support the person to be able to do it themselves.

Within the consultation it was proposed that an independent advocacy service would be required to be appointed by Manx Care to assist service users with the complaints procedure. There are some charitable organisations on the Island that already offer this service but the aim was to ensure that every service user has access to an advocacy service, if needed. Unfortunately, the Department has learned that it is unable to require this service under the Regulations. It will be a part of the longer term proposals to be established under the Reform Bill but, until that Act is developed and implemented, service users will have to rely on the charitable organisations offering that service. The Department will provide the details for those services within the guidance that it intends to publish to assist service users to navigate the complaints process.

6.1 Do you have any comments on the scope of MCALS?

This was an open question; 41 responses were received to this question.

You told us:	We Will:
17.1% of responses stated that they did not have any comments to make.	Regulations will require Manx Care to continue to provide the MCALS service.

The main themes of the other comments received include: • 29.3% of responses were suggestions for what the MCALS service should provide • 17.1% of responses concerned the current service offering or related to the access that MCALS has to other parts of Manx Care • 4.9% of responses were requests for an independent advocacy service • 31.7% of responses were suggestions for services already covered by MCALS	The operation of MCALS will be reviewed and assessed following the trial period. All consultation responses relevant to MCALS have been anonymised and shared with MCALS in order that they can be taken on board as part of the review. Regarding the comments about independent advocacy, this is a separate service that is covered later in the consultation.

6.2 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?

This was an open question; 52 responses were received to this part of the question.

You told us:	**We Will:**
3.8% of responses stated that they did not have any comments to make. There were 8 main themes concerning expectations of MCALS identified within the responses: • 26.9% of responses expect MCALS to provide signposting, general guidance and information regarding the service • 26.9% of responses expect MCALS to listen, be honest and to be compassionate and reassuring • 13.5% of responses expect MCALS to provide strong communication and acknowledgement of complaints • 11.5% of responses expect MCALS to be easily accessible, easy to use and to provide access to their personal information • 9.6% of responses expect MCALS to give professional advocacy and advice • 7.7% of responses expect MCALS to be independent from the Government • 5.7% expect MCALS to provide accountability and an apology further to complaints made	The Department believes that MCALs is a valuable service that is assisting patients and service users to resolves issues more quickly and easily. The comments have been shared for MCALs to consider alongside the other data it has collected in relation to the operation of the service for the trial period.

6.3 What services should the Manx Care independent advocacy service provide?

This was an open question; 42 responses were received to this question.

You told us:	**We Will:**

There were 7 main themes identified within the responses to this question. These were: • 19% of responses suggested extra support for vulnerable people using the service • 19% of responses suggested general assistance, advice and support with making complaints • 16.7% of responses suggested the service should be totally independent from DHSC and Manx Care, including concerns regarding the independence of the proposed service • 11.9% of responses suggested employees of the service to hold specialist legal and/or medical knowledge • 9.5% of responses suggested face to face meetings and access to a main point of contact within the service • 7.1% of responses suggested the service should cover all health and social care services • 7.1% of responses suggested the service should liaise with health and social care providers on behalf of the service user and help to mend relationships and trust	The Department remains committed to requiring Manx Care to contract with an independent advocacy provider so that a service can be offered to vulnerable people receiving services from Manx Care. This change can only be made through a new Act and so the comments will be taken into account when developing this policy area of the Reform Bill. It is intended that the service will be appointed by Manx Care and run independently from the Department and Manx Care.

6.4 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?

This was a Yes/No question; 54 responses were received.

Option	Total	Percent
Yes	**53**	**98.1%**
No	**1**	**1.9%**
Not Answered	**0**	**0%**

As a result of this feedback, the Department will be required under the Regulations to provide advice and guidance about how to make complaints.

6.5 What do you think are the best ways to provide advice, information and guidance to service users?

This was an open question; 48 responses were received.

You told us:	We Will:
The overriding opinion expressed within the responses was a need for a wide range of methods for providing advice, information and	The Department will provide a wide range of advice, information and guidance via many different communication options, including the ability to speak to someone face to face.

guidance to service users so that there is choice and accessibility. The suggestions in the responses can be grouped into 8 main areas, which are: • 45.8% of responses suggested both online and paper written information including leaflets, webpages and general published information • 25% of responses suggested in-person contact including face to face meetings and a publicly accessible office or counter • 14.6% of responses suggested email and phone communication • 12.5% of responses suggested advice/information printed on appointment or discharge letters • 12.5% of responses suggested promotion via social media • 10.4% of responses suggested accessible information, including versions in braille, audio and in various languages • 10.4% of responses suggested leaflets/posters and other media displayed or distributed within health and social care settings • 8.3% of responses suggested promotion of the service within community hubs and through drop-in information sessions	

7. A simpler process for making complaints

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

This was an open question; 45 responses were received, which are summarised below.

Informal early resolution of issues: At consultation, it was proposed that issues that are raised orally with a staff member of a service provider (either through MCALs or directly with the staff member that is providing care) do not need to be considered as formal complaints if they are resolved satisfactorily within 3 working days. All other issues (including those raised orally and not resolved) 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.

This 3 day period was generally supported by respondents but some people raised issues with the practicalities of implementing it. The Department acknowledges that this proposal could result in a situation where the staff member providing the care believes that the issue is resolved but it has not been resolved to the patient's satisfaction. The Regulations will be updated to ensure that, if this is the case, the complaint can be raised formally with the service provider.

The best way to resolve the practical issues would be for all concerns or oral issues raised to be logged as a concern/enquiry. This could then be escalated to a formal complaint, if there is a continuing issue that needs investigating. This suggestion will be covered by guidance to be issued by the Department on model complaint handling.

In relation to issues that become complaints, it is intended that there should be an easy to follow and accessible process for any complaint about a health or social care service made to Manx Care (or another provider) about the services provided under the mandate from the Department, as follows:

Local resolution: Initially, complaints should be made to the provider of the service. The service provider will investigate and issue a formal response to the complainant.

Independent Review: If the complainant is not satisfied with the outcome of the investigation at local resolution, or if the investigation has not been completed within 3 months, a review of the process can be requested from the Health and Social Care Ombudsman Body.

You told us:	**We Will:**
17.8% of responses stated that they did not have any comments to make. 20% of responses expressed approval and support of the proposed process 15.6% of responses were complaints about the current process 6.7% of responses did not support the proposed process 6.7% of responses expressed concern about staffing and timescales The remaining 33.3% of responses provided suggestions. These included: • Use of simple language and accessibility • Logging of all issues and incidents • Objectivity and independence • Reduction to proposed timescales • Easy to access information/advice	The Regulations will set out the process to be followed in relation to investigating formal complaints at both local resolution and independent review stage.

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

The proposed transition period was 6 months from when the Regulations are approved. Time is required between the Regulations being approved and the changes being implemented because new Ombudsman body members will need to be appointed and documents will need (re)writing and publishing.

This was an open question; 34 responses were received.

You told us:	We Will:
29.4% of responses stated that they did not have any comments to make. 35.3% of responses expressed support of the proposed transition period 11.8% suggested the proposed transition period was too long 2.9% suggested the proposed transition period was not long enough 20.6% of responses expressed concerns not related to the transition period. The concerns included guidance for service users and providers, flexibility of the period and the potential implications/delays caused by the diversion of resources within services to achieve the changes within the period.	The Department has decided that the transition period for bringing in the Regulations will be 3 months after the Regulations have been approved by Tynwald (October 2022). Regarding concerns that the transition period is too long, the Department is aware that Manx Care is already working on making improvements to its complaints arrangements and these improvements are aligned to the proposals set out in the consultation. Further communications with all service providers is planned to ensure that they have as much notice as possible to implement the changes.

8. Making a complaint about a service

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

This was an open question; 43 responses were received.

The main changes proposed within the draft Regulations that were consulted on were:

- the **timescale for making a complaint was extended** to 12 months of the person becoming aware of the matter that they wish to complain about; and
- the **timescale for acknowledging a complaint was increased** from 2 working days to 5 working days to allow time for some additional information to be provided in the acknowledgement letter.

Complaints may be made on a person's behalf in certain circumstances. The wording in relation to the person that can complain was not proposed to be changed from the current Regulations; however, it was pointed out during the consultation that the requirement for the person to be a relative or a person that has "sufficient interest the welfare of the person and is a suitable person to act as representative" may not be the best solution as no test is set out for the complaints manager to be able to determine when a person has sufficient interest.

The wording in the Regulations will be amended to remove the limitations on who can be a person's representative (so that relatives are not expressly mentioned) and focus on whether the representative is conducting the complaint in the best interests of the person on whose behalf the complaint is made. A best interest decision is a decision made by applying the Best

Interest principle, as set out in the UK's Mental Capacity Act 2005 (and as proposed in the Island's draft Capacity Bill).

For consistency, the same wording will be used for complaints being made to the Ombudsman body.

You told us:	We Will:
23.3% of responses stated that they did not have any comments to make. 30.2% of responses were supportive of the proposed changes 16.2% of responses concerned timescales for acknowledging complaints or timescales for complaints more generally 11.6% of responses concerned how the acknowledgement would be communicated 7% of responses concerned accessibility/representation for vulnerable service users 4.7% of responses concerned the requirement to pursue best practice in the proposed changes 4.7% of responses were not supportive of proposed changes 2.3% of responses were concerned with ease of access to medical records	The majority of responses were in support of the proposed changes to the timescales so these will remain. A change to the Regulations will be made in relation to who can act as a complainant's representative as outlined above.

9. People dealing with complaints

"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.

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

This was an open question; 49 responses were received.

You told us:	We Will:

18.4% of responses stated that they did not have any comments to make. 55.1% of responses were in agreement with the suggestions and reiterated the importance of training Manx Care staff in dealing with complaints. 16.3% of responses expressed concern regarding staff culture and attitude towards complainants. 8.2% of responses expressed concern regarding the funding of the proposed training or other potential costs or staffing requirements.	The Department will retain the requirement for training within the draft Regulations. The Department acknowledges that a change in culture is a vital aspect in improving complaints handling. This cannot be fixed through legislation alone but work is underway to improve the culture within Manx Care, supported by the workforce and culture project, which is in place as part of the Heath and Care Transformation Programme to deliver on Sir Jonathan Michael's 25th recommendation. There are work streams in progress which focus on the values of Manx Care as an organisation, creating psychological safety in the workplace, creating a learning culture, recognition activities and wellbeing opportunities for Manx Care employees.

10. Investigating the complaint and keeping the complainant informed

10.1 Do you agree with the additional requirements?

It was proposed that the current requirements are 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).

This was a Yes/No question; 53 responses were received.

Option	Total	Percent
Yes	**49**	**90.7%**
No	**4**	**7.4%**
Not Answered	**1**	**1.9%**

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

This was an open question; 16 responses were received.

The feedback indicated that face to face meetings with complainants are a helpful way to communicate and resolve issues (in addition to formal written communications). The process outlined in the draft Regulations already included a meeting to be offered to the complainant at the start of the process so that they have a chance to discuss the complaint. Post consultation, it is recommended that a resolution meeting is also offered to the complainant after the final response has been sent. This would increase the accountability of the service provider in relation to the final responses that are sent.

A number of responses mentioned a lack of support for complainants after having gone through the process, with one respondent suggesting that therapy or counselling should be offered as standard. It is intended that the Regulations include a requirement that the formal response letter to the complainant includes an offer to supply the complainant with details of any services or support which it considers may provide assistance to the complainant, taking into account that person's needs.

Some consultation responses asked for more support for staff to be included in the proposals. Within the Manx Care (Duty of Candour) (Procedure) Regulations 2021 there is a specific requirement for staff are supported if directly involved in an incident. It is proposed that similar wording will be inserted into the draft Regulations so that service providers are required to offer support for staff members that have been complained about.

You told us:	**We Will:**
25% of responses concerned legal action and legal liability 25% of responses expressed dissatisfaction with the current process 12.5% of responses expressed overall agreement with the proposals 12.5% of responses expressed the requirement for an independent service 12.5% of responses suggested the need for a supportive and open service 12.5% of responses made suggestions that were out of scope or not applicable to the Regulations	The majority of people agreed with the additional requirements so these will remain in the Regulations. Additional sections will be added to the Regulations to take into account the feedback received about: - a face to face meeting following the final response; - an offer of support for complainants; and - an offer of support for staff that have been complained about.

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

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, investigations should continue to try to resolve the complaint unless there are compelling legal reasons not to do so. It is intended that this should be the case on the Island and so 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).

This was a Yes/No question; 53 responses were received to this part of the question.

Option	Total	Percent
Yes	**51**	**94.4%**
No	**2**	**3.7%**
Not Answered	**1**	**1.9%**

10.4 If you disagree, please provide further comment

This was an open question; 9 responses were received.

You told us:	We Will:
55.6% of responses stated they agreed that investigations into complaints should continue even if the complainant intends to pursue legal action. Reasons included the duty of candour and responsibility to service users and to remain fair and transparent. 22.2% of responses did not state agreement or disagreement but placed value in ensuring the initial investigation is dealt with quickly, effectively and services learn from the complaints. 11.1% of responses stated they disagree with investigations into complaints continuing if the complainant intends to pursue legal action because continuing the initial investigation would not be the best use of time and resource if it is to be superseded by the legal action. 11.1% of responses were not applicable to the question as they concerned the investigation by the independent review body and not the service provider.	The majority of responses were in support of complaints continuing to be investigated properly and responded to if the complaint is also planning to take legal action and so this exemption will be removed in the final version of the Regulations. The exemption for complaints by a member of the public not to be dealt with if the service provider is taking, or proposing to take, disciplinary action against a staff member whose actions are the subject of the complaint will also be removed as a result of the consultation responses received.

11. Formal response to the complainant

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.

A backstop of 6 months for a final response to be issued will also be included in the Regulations to encourage timely responses to be issued. If a complainant feels that the service provider is not taking appropriate action to resolve the complaint within the timescales agreed, there will be the ability for the complainant to escalate their complaint to the Ombudsman body after 3 months.

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

This was a Yes/No question; 53 responses were received to this question.

Option	Total	Percent
Yes	**46**	**85.2%**
No	**7**	**13.0%**
Not Answered	**1**	**1.8%**

11.2 If you disagree, please provide further comment

This was an open question; 13 responses were received.

You told us:	We Will:
38.5% of responses thought the 20 day timescale was too short. Reasons included that it is not long enough for complex cases and that each investigation should be bespoke. 15.4% of responses were not supportive that the 20 day timescale would be achievable or adhered to. 23.1% of responses thought the 20 day timescale was too long. Reasons include limiting stress and anxiety for the complainant. 23.1% of responses to this question actually agreed with the proposed 20 day timescale.	The majority of respondents agreed that a 20 day standard timescale, with the ability to extend that in more complex cases where a longer investigation is required, is the best option and so this will be retained within the Regulations. An additional requirement that the final response must be issued within 6 months will also be added to the final Regulations.

12. Requesting a review from an independent body

Within the consultation, it was proposed that a combined Independent Review Body ("combined IRB") called the Health and Social Services Independent Review Body would be

established. This section of the consultation paper set out the proposals for this new body but did not ask any specific questions.

The Department has considered the responses to part 1 and part 2 of the Complaints Modernisation consultations in the round, along with the practicality of setting up a new IRB for an interim period. Following this it has decided that it would be of greater benefit to the public to move towards setting up an Ombudsman at the earliest opportunity.

The Department's preference would be for an independent Ombudsman with the remit to review unresolved health and social care complaints to be appointed independently from the Department and Manx Care. However, it is not possible achieve this within the Regulations; therefore as an interim solution, an Ombudsman body will be established, which will be funded by the Department but operate independently with members appointed by the Appointments Commission. It will be completely independent from the bodies about which it will review complaints (Manx Care and other service providers).

13. Who will be members of the combined IRB?

13.1 What are your views about the proposed membership of the combined IRB?

It was proposed at consultation 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. The members should have relevant experience in health, social care, dispute resolution or administrative justice. At least one of the members will be required to be a health care professional and at least one of the members will be required to be a social worker.

Consideration was given to whether some of the combined IRB members could be from outside the Island to 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.

This was an open question; 45 responses were received.

You told us:	**We Will:**
The responses provided a wide range of suggestions regarding the proposed membership of the combined IRB which can be divided into 7 clear groups: 26.7% of responses thought the IRB should include members who are professionals in healthcare, social care and law. 20% of responses voiced agreement with the proposals in the consultation	The Department intends to set up a Health and Social Care Ombudsman body within the draft Regulations. A change will be made to the Regulations to give more flexibility for the Appointments Commission to determine the number of members that can be appointed to the Ombudsman body. It is proposed that between 7 – 10 members can be appointed in addition to the chairperson. This will allow for more or less members to be appointed until the workload of the Ombudsman body is known.

17.8% of responses thought the IRB should be completely independent from the government 17.8% of responses thought the IRB should include members from off-island in order to provide impartiality and diversity 8.9% of responses thought the IRB should be made up of local members 8.9% of responses thought the IRB should include lay members as well as professionals. 6.7% of responses thought that the proposed number of 9 members of the IRB was too high given the size of the Island's population.	The Regulations will be amended to remove any limitations to the members needing to be based on Island.

13.2 What are your views about the proposed requirements in respect of experience, qualifications and training of members?

This was an open question; 43 responses were received.

You told us:	**We Will:**
The responses provided a wide range of suggestions regarding the proposed requirements in respect of experience, qualifications and training of members: 27.9% of responses focussed on the requirement for members to have professional qualifications in healthcare, social care and law and comprehensive experience in these type of roles 25.6% of responses generally agreed with the proposed requirements, reiterating the importance of training and experience 18.6% of responses highlighted the requirements for members to be trained thoroughly in all procedures and background of the Manx systems as well as training to ensure sensitivity and fairness for service users making complaints and for service provider staff that the subject of the complaint 9.3% of responses were not relevant to the question topic 4.7% of responses suggested qualifications and experience were not essential attributes for the members and lay members would be preferable. The remaining 14.0% of responses were alternative responses, including suggestions that IRB members can use external specialist advice	It is proposed that the members of the Ombudsman Body will be required to have relevant experience as the Appointments Commission 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 be a social worker. A recently retired health care professional or social worker will also be allowed to become members of the Ombudsman Body. The proposed chairperson will be required to be legally qualified with 7 years' experience, which is aligned to the experienced needed to become a tribunal chair. Additionally, there will be the ability for the Ombudsman to request expert advice in relation to a specific complaint, if required. In terms of the training of the members, this will be required to be arranged by the Ombudsman body.

and that the format of the IRB should be more similar to a tribunal or ombudsman.	

13.3 Do you think that any ongoing training requirements (for members of the Ombudsman body) should be set out within the Regulations?

This was a Yes/No question; 50 responses were received.

Option	Total	Percent
Yes	43	**79.6%**
No	7	**13.0%**
Not Answered	4	**7.4%**

13.4 Do you think that any ongoing training requirements should be set out within the Regulations? - Please provide reasons for your response

This was an open question; 41 responses were received.

You told us:	We Will:
The reasons for answering no to be above question included: - Requirement for flexibility around training - It should be a process that develops and evolves over time - Individual training needs may vary The reasons for answering no to the above question included: - Training should be undertaken regularly - Training should ensure independence and impartiality - Training should help to maintain high professional standards - Learning outcomes from complaints should be used for training purposes - To provide reassurance and support for service users and staff - To ensure timescales are adhered to 9.8% of responses provided alterative suggestions including undertaking accredited qualifications and the publication of all training requirements and training undertaken by members.	It is proposed that a requirement to undertake regular training is set out in Regulations along with a requirement for the Department to fund this training. Any detail in relation to the training requirements will be set out in guidance by the Department rather than within the Regulations to give flexibility and to be able to vary it as needed. The Ombudsman body will be required to report on the training undertaken by the members during the year within its annual report.

14. What will the combined IRB's role be?

It was proposed that 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.

It was proposed that the combined IRB would be able to review the organisation's actions in relation to complaints where the final response had not been issued within 6 months of the complaint being made or where the organisation that provided the service had declined to review the complaint because it has not been made to it within the 12 month time frame.

The time limit for making a complaint to the combined IRB was proposed to be within 1 year from 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 was also flexibility provided, at the discretion of the combined IRB Chairperson, in respect of this timeframe.

It is intended that the Health and Social Care Ombudsman Body would have the same remit as originally proposed for the combined IRB. As mentioned above, the time frame for submitting a complaint to the Ombudsman body if the complainant is not happy with the progress being made by the service provider has been shorted to 3 months. The aim of this is to try to encourage prompt responses to complaints.

The time limit for making a complaint to the Ombudsman body is also proposed to be extended slightly to allow for the fact that complaints to both the service provider and the Ombudsman body are within a year of the complainant becoming aware of the problem. This could cause the complaint to be timed out of the Ombudsman body if the complaint was made to the service provider in the 12th month. Therefore, further flexibility will be allowed under the Regulations so that complaints can be made to the Ombudsman body within 6 months of the final response being issued by the service provider (even if this is longer that the 12 month time frame).

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

This was an open question; 35 responses were received.

You told us:	**We Will:**
48.6% of responses stated that they did not have any comments to make. 25.7% had concerns or comments regarding the time limit for making a complaint, mostly that the time limit needs to be flexible and established on a case by case basis. 17.1% were comments in support of the proposed time limit 5.7% of responses were not supportive of the proposals 2.9% of responses were views not directly related to the question	The proposed combined IRB will be replaced by a Health and Social Care Ombudsman Body. The Regulations will be amended to allow a complaint to be made to the Health and Social Care Ombudsman Body within 12 months of becoming aware of the problem or within 6 months of the date of the final response to the complaint being sent by the service provider, whichever is longer. Flexibility is also given to the chairperson of the Ombudsman body to decide to extend the time limit on a case by case basis.

15. Making a complaint to the combined IRB

The draft Regulations included a requirement for a requests for an independent review of a complaint to be submitted on a standard form; however, it is acknowledged that in some cases this may not be possible and so complaints should be allowed to be made orally, if necessary. A change is proposed to ensure that the requirements allow easy access to the Ombudsman body, whilst still encouraging the use of the standard form.

Once a complaint has been received it was proposed that the combined IRB would acknowledge the complaint within 5 working days. The combined IRB would then be required to carry out initial checks to make sure that it is a complaint that falls within its remit and decide on the best way for it to be dealt with. During this time a meeting would be offered to the complainant in order to hear more about the complaint and a high level review would be carried out against some standard considerations, which are listed within the draft Regulations.

It was proposed that the combined IRB would 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 within 20 working days. If the combined IRB could not review the complaint, it would be required to explain why and set out what other options might be open to the complainant.

The proposals suggested in this section were supported on the whole and so they will apply to complaints made under the Ombudsman body, subject to the changes outlined in the table below.

15. 1 Do you have any comments on the proposed process or standard considerations for the initial review?

This was an open question; 36 responses were received.

You told us:	We Will Do:
38.9% of responses stated that they did not have any comments to make. 19.4% of responses agreed with the proposed process 19.4% of responses thought considerations should include alternative communication approaches and publicity for the service, as well as accessibility and help with filling out forms and using the service. 22.2% of responses contained a variety of other suggestions including timescales, external reviews, internal review processes and IRB record keeping.	A change will be made to the Regulations to ensure that complaints can be submitted orally, if someone has difficulty with making a complaint in writing. A further change will be made to require the Ombudsman body to set out its understanding of the complaint at this stage. The standard considerations have been subject to internal review and the drafting will be amended to make them easier to understand.

16. Reviewing the Complaint

It was proposed that the combined IRB would gather all of the information needed from the complainant and the service provider. The draft Regulations allowed the service provider 6 weeks to provide the information. The consultation responses indicated that this was too long a timeframe for complainants to wait and so a change is suggested so that the information must instead be provided within one month. This changes brings the provision of information requirement in line with the timescales for responding to a data protection subject access request. 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 Ombudsman body. Again, the timeframe for this has been aligned to the timescales for responding to a data protection subject access request.

The proposals also allow the Ombudsman body to convene a hearing to take oral evidence or advice in relation to the complaint. The draft Regulations provide a right for any person who is giving evidence before the hearing to be accompanied whereas presently, only complainants have that right. People giving evidence or advice to the Ombudsman body can be accompanied by another person, which could be a friend, a carer, a legal representative or an independent advocate. We have looked into whether legal aid is available for supporting people in making representations to the Ombudsman body and unfortunately it is not. The availability of legal aid to assist people with this process will be considered further under the Reform Bill.

Once the information has been received, the Ombudsman body will consider the handling of the complaint by the service provider against the procedure set out within the Regulations and decide whether the service provider's response was reasonable and appropriate. Where necessary, independent expert advice will be sought in relation to the subject matter of the complaint. Following the review, the Ombudsman body will be able to uphold a complaint, no uphold a complaint or refer the matter back to the organisation that provided the service for further action.

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

This was an open question; 35 responses were received.

You told us:	We Will:

22.9% of responses stated that they did not have any comments to make. 22.9% of responses agreed with the proposed process 14.3% of responses were concerned the 6 week time scale was too long 8.6% of responses concerned the giving of evidence, asking for oral evidence to be considered and if a service provider could be represented by a legal professional or accompanied by another person. 31.4% of responses contained a variety of other suggestions, covering impartiality, initial review by a single IRB member, appeals, feedback and publishing.	The 6 week timescale has been reviewed and an alternative suggestion has been proposed within the draft Regulations which brings the timescales for information to be provided into line with data protection subject access requests. The Regulations will require the Ombudsman body to set out the process used within a code of practice that is available to the public. It is anticipated that this will follow the best practice guidelines issued by the Scottish Public Services Ombudsman.

17. Final decision

The proposal within the consultation was 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. A report will be issued that summarises the findings and recommendations for action to be taken to resolve the complaint. This will be required to be made public, unless there are issues in relation to safeguarding vulnerable persons and in order to protect the interests of the complainant.

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 recommendations will be made about what the organisation should do to rectify this.

It was proposed that the combined IRB's decision will be final and there will be no recourse for appealing against that decision other than by judicial review.

However, there was a new requirement proposed 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 was only in relation to the process that has been followed in considering the complaint and not a mechanism through which complainants could appeal the decision of 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.

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

This was an open question; 34 responses were received to this part of the question.

You told us:	We Will:
29.4% of responses stated that they did not have any comments to make. 26.5% of responses were supportive of the combined IRB having the final decision 11.8% of responses were not supportive of the proposal and thought it was unfair that the IRB would have the final decision on a complaint 11.8% of responses were generally supportive but highlighted a need for accountability, fairness and integrity in the process as well as unbiased reporting. 5.9% of responses were generally supportive but had concerns regarding the enforcement of the final decision and any recommendations made. 14.7% of responses had other concerns and queries, including availability for Legal Aid for complainants throughout the process, how many complaints will be upheld and what options are available in situations that fall outside the IRB's remit.	Review mechanisms need to have a final end point and so it has been decided that the decision made by the Ombudsman body will be final and no further review stage will be allowed (other than to seek legal redress). If a complainant is unhappy with how the review of the complaint has been carried out then the Ombudsman body will have a published complaints process that the person can follow to ensure that his or her complaint has been fairly considered. To ensure that recommendations are acted upon, mechanisms for increased transparency and accountability for implementing the recommendations of the Ombudsman body have been included within the Regulations, including: • the Ombudsman body being required to report to Tynwald annually on any recommendations that have not been implemented; • it becoming standard practice for anonymised versions of the Ombudsman body 's reports to be made available publicly; • Manx Care being required to state publicly if they are unable or unwilling to implement the recommendation and to give a reason for not implementing it; and • the DHSC will be required to hold Manx Care to account in implementing the recommendations.

17.2 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?

This was a Yes/No question; 49 responses were received to this part of the question.

Option	Total	Percent
Yes	31	**57.4%**
No	18	**33.3%**
Not Answered	5	**9.3%**

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

This was an open question; 28 responses were received.

You told us:	We Will:
17.9% of responses thought the role should be fulfilled by a legal professional such as an advocate or a Deemster 17.9% of responses thought the role should be fulfilled by an independent body, ideally off-island 14.3% of responses thought the role should be fulfilled by the Department, the Health Minister or another Governmental department 7.1% of responses thought the role should be fulfilled by the Tynwald Commissioner for Administration 7.1% of responses thought the role should be fulfilled by an independent ombudsman 7.1% of responses were unsure who should fulfil the role 25.0% of responses were not recommendations for who should fulfil this role but what value the review would add. For example, to step in if the IRB makes a mistake or to ensure full transparency, accountability and impartiality. It was also suggested such a review should only be used in exceptional circumstances or only to review the handling of the complaint rather than the subject matter of the complaint itself. 3.6% of responses felt the role was not required and would undermine the credibility or the IRB.	The Department agrees that to set up any further review mechanism would undermine the credibility of the Ombudsman body. Therefore the Department intends to retain the position that the decision of the Ombudsman body cannot be appealed or reviewed other than by recourse to legal challenge, such as judicial review.

18. Learning from complaints

A new requirement for the service provider to demonstrate that it has learned from the complaints received was 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.

18.1 Do you have any views about the new regulation to address learning from complaints?

This was an open question; 39 responses were received to this part of the question.

You told us:	We Will:
17.9% of responses stated that they did not have any comments to make. 28.2% of responses were supportive of the new regulations to address learning from complaints 15.4% of responses had concerns about implementation and wanted to make sure all recommendations further to complaints were learnt from and implemented 10.3% of responses thought that the culture across health and social care workforces was a key issue that needed addressing in order to ensure learning from complaints and improvements in care 7.7% of responses thought accountability was key in order to facilitate learning from complaints 5.1% of responses were not supportive that the new Regulations would be able to exact the change required 15.4% of responses addressed a variety of concerns including support for complainants, disciplinary procedures for staff that do not comply and the recording of information to aid learning.	The Department agrees that learning will need to take place throughout the organisations and that a culture change may be required in some areas to implement the changes being suggested within the legislation. The Department supports the work being done by the Transformation's Workforce and Culture project in this regard (see section 9.1 for further information).

19. Transparency, Accountability and Assurance

It was proposed that the Department, Manx Care and the combined IRB would be held to account through public reporting requirements 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.

19.1 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?

This was an open question; 41 responses were received.

You told us:	We Will:
24.4% of responses stated that they did not have any comments to make. The other responses can be split into 8 categories. These were: • 34.1% of responses wanted to see a wide range of statistics in the annual reporting • 24.4% of responses wanted to see evidence of implementation, accountability and learning outcomes in the annual reporting • 9.8% of responses wanted annual reporting to be fully transparent • 7.3% of responses wanted to see information about time spent dealing with complaints or details about any cases were timeframes were not met • 7.3% of responses wanted the annual reporting to be done with sensitivity and ensuring the privacy of all involved • 4.9% of responses wanted the annual reporting to be accessible and user friendly • 4.9% of responses stated they supported the proposals • 2.4% of responses were not supportive of the proposals	Annual reporting from the Department to Tynwald will be required in the Regulations. The report will be made up of the report supplied to it by Manx Care (in relation to complaints about all mandated services) and an assessment of Manx Care's performance in relation to complaints handling during the reporting period, including information on Manx Care's implementation of the recommendations of the Ombudsman body. It is proposed that the report from Manx Care (and other service providers) will cover the following items broken down by area of care: • the numbers of complaints received • the subject matter of those complaints • a summary of how they were handled including the outcome of the investigations into those complaints; • a statement outlining changes or improvements to services or procedures as a result of consideration of complaints. The Ombudsman body will also be required to compile a report and submit it to the Department to be laid before Tynwald. Changes have been made to the Regulations to align all of the timescales for reporting so that all complaints report will be submitted to the same sitting of Tynwald so that they can be considered as a package. An additional requirement for the Ombudsman body's report will be that it covers information in relation to outstanding recommendations, including how long those recommendations have been outstanding. The annual reports will be made public.

19.2 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?

This was an open question; 48 responses were received.

You told us:	We Will:
12.5% of responses stated that they did not expect to see annual reports, with some	Post consultation it has been decided that annual reports from all service providers will be

suggesting that though it could be encouraged it is not necessary by regulation All other responses were in support of annual reports and the proposals; • 56.3% of responses provided no additional comments • 14.6% of responses thought annual reporting was required as a means of providing transparency and accountability • 12.5% of responses thought annul reporting was required to demonstrate the implementation of recommendations and evidence of changes made as a result • 2.1% of responses thought annual reporting needed to be flexible dependent on the size of the service provider and/or resource available to them • 2.1% of responses thought annual reporting was required in order to help promote a change of culture in Manx Care	required to be provided to Manx Care to be included within Manx Care's annual reporting. Manx Care's annual report will be made public. Some service providers are small organisations and so to require them to publish their annual reports individually could inadvertently disclose sensitive personal information about a service user.

20. Equal Opportunities

An initial assessment of the complaints arrangements set out within the Complaints Regulations identified 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).

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

This was an open question; 30 responses were received to this question.

You told us:	**We Will:**
46.7% of responses stated that they did not have any further comments to make. 20% of responses thought that accessibility had the most potential risk to affect equality of opportunity and so ease of access, plain and clear language, support for vulnerable service users and availability of information in a variety of languages and accessible formats were needed	Changes will be made to the Regulations in relation to the process of making a complaint to ensure that it is not discriminatory against those that would not be able to submit a written complaint. The Regulations will be implemented in line with equality legislation and policies.

13.3% of responses thought that sensitivity and respect for service users, particular concerning mental health needs, was vital to ensuring minimal potential risk to affect equality of opportunity 6.7% of responses were supportive of the proposed policy 13.3% of responses provided alternative potential risks to equality of opportunity including transparency, data protection and diversity issues	

21. Any other comments

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

This was an open question; 35 responses were received to this question.

You told us:	**We Will:**
11.4% of responses stated that they did not have any further comments to make. 28.6% of responses were supportive of the proposals set out within the consultation 17.1% of responses reiterated the importance of supporting staff and ensuring sufficient staff training around complaints 8.6% of responses were not supportive of the proposals set out within the consultation 5.7% of responses thought the consultation was too long 28.6% of responses covered a variety of other feedback including: separation from politics, ensuring respect of the IRB's powers, need for transparency and a culture of accountability and the need to ensure as much is done at local resolution to avoid escalation to the IRB	In order to assist staff with dealing with complaints, training requirements are covered in the Regulations. Additionally, a change is proposed to ensure that staff that are complained about receive a debrief following the investigation and are offered any necessary support.

Appendix 2

Complaints Modernisation Part 1 - Breakdown of Consultation Hub Responses

Please note that only responses with permission to publish are listed within the tables in this appendix; however, all responses were factored into the main themes identified.

Q.1.1 Do you have any comments on the scope of the Manx Care Advice and Liaison Service?	
You Told Us:	**DHSC Response:**
No I hope you will listen to people when they put in complaints my complaint is before Manx care was formed.	Agreed
The scope should be as wide as possible.	Noted
Yes it's not good at the moment	Noted
They must be listened too and consultants must respond to concerns promptly	Agreed, MCALS staff work to open communication channels between the public and the care providers to help resolve issues.
No	None
It should provide Advocacy	Noted. However, it is considered that advocacy should be offered independently to Manx Care so it will not be offered by MCALS.
Advice. Information about all available services provided.	Noted
No	None
any person who has substandard care in any way from any department should be able to seek help across the whole scope of the service	Agreed - MCALS operate across whole of Manx Care
No	None
Shouldn't they have unlimited access to government documents as well as patients to give informed clear advice	MCALS do have access to all departments within Manx Care.
What actions will you be able to take? IRB can do nothing but recommend, and it seems that recommendations have yet to be enacted. Manx Care should have more 'teeth and be able to effect changes, otherwise there is no point to its existence.	Whilst this is true, it is not relevant to the advice and liaison service.
Those providing this service should be given access to all departments to gain accurate information on current procedure directly on behalf of their client, if necessary.	Agreed, this is currently the case.

The only comment I have at the moment is that there is very little information on how to contact Manx Care Advice. When looking through the Manx Government website it only states that you must contact the secretary of Manx Care Advice who will then pass your correspondence onto the board. I feel that an address contact would be better.	This comment appears to be relevant to the current NHS IRB rather than MCALS. There is a phone number and email address provided on the website for contacting MCALS. In future, the Ombudsman body will be required to publish its contact details.
No recent need for this services under the new regime but hopefully clearer processes are made available to patient on which way to proceed	None
No	None
If they don't have the remit to deal with something to be able to pass it on to someone who does.	Agreed - no change needed
Recognition of when to pass things up to management	None
Firstly, according to the website, MCALS is only open between 10am and 3pm on weekdays. For those people without internet access this could be a problem. Also, people may be unsure as to the role of MCALS as it is described as a "service which aims to improve patient and service user experiences by helping to sort problems out quickly, providing advice and pointing people in the right direction to get the help they need." However it "cannot help people with the provision of medical advice or diagnosis, counselling, advocacy or formal complaint resolution". I think a simple, clear explanation of the service should be provided to avoid confusion.	Currently the phone lines are open between 10am – 3pm but MCALS staff are working outside of those times looking into queries and answering emails. In the longer term, Manx Care would like to consider extending the hours that the phone lines are open and providing face to face advice to provide increased access to the service. There was a lot of confusion in the consultation about the different roles of the various parties so the consultation response will aim to simplify language to help people understand the role.
It should be operating entirely independently from Manx care and DHSC	MCALS is an internally operated service. The benefits of this are that MCALS staff know who to contact and where to find the necessary information to be able to help people address concerns quickly and simply.
Locating and providing information and answers to queries. - Communicating concerns expressed by members of the public to specific services and/or escalating to senior management where appropriate. - Provide guidance and signposting to other information sources and help available	Agreed this is part of the current scope of MCALS.
could not be any worse than the advice and liaison service prior to Manx care being established	Noted
I think it should cover all areas of Health and Social Care.	Agreed
Prompt action. Meetings if required. Candour. Transparency. Timescale for action by regulation. My understanding is that this service is to assist the public get through the system and answer questions. If the service becomes busy then service will deteriorate. Monthly or quarterly published statistics. I appreciate that Manx Care launched this	Noted - more publicity needed. The operation of the service will be reviewed and assessed following the trial period. All consultation responses relevant to MCALS have been anonymised and shared with MCALS in order that they can be taken on board as part of the review of the service following the trial.

service with news articles but the general public still don't know about it and it should be advertised more. Perhaps try tweeting or Facebook on a regular basis that that MCALS are there. Do they have a leaflet given out to the public or in departments? Do cancer patients get told about the service and provided with a leaflet by oncology on the first visit?	
I would like it to be almost a patient coordinators role whereby they liaise between the patient and practitioner improving communication , consent and reducing complaints	Agreed, this is the role of MCALS.
I complained some time ago about my time in A&E the reply was not helpful and it Took ages to get a response which in my mind was very unsatisfactory	Noted, the change proposed aim to improve the timeliness and quality of responses to complaints.
I am totally against a whole department of people being recruited for this task with money being taken unnecessarily from the medical budget.	Noted. The operation of MCALS will be reviewed and assessed following the trial period. All consultation responses relevant to MCALS have been anonymised and shared with MCALS in order that they can be taken on board as part of the review of the service following the trial.
Excellent service Needs to have more staff so the service can be expanded and not such a limited time	Noted. The operation of MCALS will be reviewed and assessed following the trial period. All consultation responses relevant to MCALS have been anonymised and shared with MCALS in order that they can be taken on board as part of the review of the service following the trial.
It should not be a comfy option for staff who can't cut it in the real world. They should be measured on outcomes and change.	Agreed, data is being recorded by MCALS to review the impact that it is having during its trial period.
Does it have teeth? How will MCALS turn a complaint into an opportunity for service improvement?	MCALS is a confidential help and advice service run by Manx Care that aims to improve patient and service user experiences by helping to sort problems out quickly, providing advice and pointing people in the right direction to get the help they need. In doing so, it is felt that many concerns will not escalate into formal complaints; however, MCALS will help people to understand their options and offer reassurance to people that making a complaint is sometimes the right way forward and won't affect their care. In those cases, people will be given advice on how to make a complaint. It will be for the complaints team to investigate and suggest improvements to the service area.
MCALS is a fabulous initiative that could provide: Advice re Manx Care services Reassurance re any concerns Updates on appointments Deal with and escalate complaints	Noted

Important that it covers all services provided or contracted by Manx Care.	Currently, MCALS has access to all Manx Care services; however following the trial period, the service will be reviewed and your comments regarding broadening the scope has been provided to them for consideration.
I think it is right that they can provide information and should be able to signpost people to how to make a formal complaint if required. I feel it is right that this is where their remit ends. Complaints and advocacy should be separate to MCALS	Noted

Within the responses received, there were 4 main elements related to the following themes:

1 Suggestions as to what the MCALS service should provide (29.3%)
2 Comments regarding the current MCALS service and its relationship with the rest of Manx Care (17.1%)
3 Requests for an independent advocacy service (4.9%)
4 Suggestions that are already provided by MCALS (31.7%)

Q.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?	
You Told Us:	**DHSC Response:**
To explain the system, to be sympathetic to be caring and helpful.	Agreed
Fully access to my medical data/information	MCALS could advise you on the correct process to request your medical record.
Having had multiple complaints that I reported that I do not believe were ever looked into as a few weeks after I put complaints in the case on their end was closed and the person that I was to report it too said on their 2 inspections that they didn't find anything and what I was saying was serious but was treated as if I was lying they said "what do you expect us to do put secret cameras in" I feel in most care settings the announced and unannounced inspections don't work as they see you at door before letting in and then people get warned if unannounced and people will then be on their best behaviour having seen this happen.	Noted, the new process aims to ensure that complaints are listened to and learned from.
Would expect guidance on the process and to act as patient advocate for support in gaining resolution (in whatever form) to the complaint.	MCALS staff cannot act as patient advocates but advise the person how to access additional help and support. Independent advocacy
To be listened to; to attend a meeting to discuss the situation open and frankly; not to feel intimidated by overuse of paperwork and jargon by the Service; to actually feel that I matter and that something would come out of the complaint/issue to improve the service.	Agreed
To actually make it easier to make a complaint and find the forms easier	Agreed
Listen to concerns and facilitate a resolution to a problem	Agreed

Reassurance as to where the process of the complaint was up to. I was passed from pillar to post with no acknowledgement of the delays despite their pathway.	Agreed
I would expect guidance, assistance, support AND ADVOCACY	Advocacy to be provided separately (independent from Manx Care) but MCALS could signpost people to this service if additional support was required.
Information and advice Signposting towards making a complaint What about lack of service such as dentistry or community health services?	Agreed that information, advice and signposting towards making a complaint would be covered by MCALS. In relation to a lack of a service, if such an issue was raised MCALS would help the service user to communicate with the relevant Department to access the service or to be added to a waiting list or explain why such a service is unable to be offered.
Communication Timeliness Fairness Accountability	Agreed
yes and it to be acted on, not just ignored	Noted
Easy access by variety of communication options as many service users don't have transport, internet, and reliable phone signal. sight language and hearing problems need to be catered for	Currently phone and email are the only ways to contact MCALS during the trial period. Following the trial period, the service will be reviewed and your suggestion has been forward for consideration. MCALS would like to be able to provide a face to face service in future.
I've had a complaint on going since December last year. Clear in person advice and liaison. Would be invaluable. Make the process clearer, smoother. And hopefully quicker. To actually speak to someone in person about my concerns Would go a long way	Currently phone and email are the only ways to contact MCALS during the trial period. Following the trial period, the service will be reviewed and your suggestion has been forward for consideration. MCALS would like to be able to provide a face to face service in future. MCALS could help you to communicate with the complaints team.
Easily accessed. Weeks not months to deal with cases.	Agreed all issues raised with MCALS are resolved within 7 days.
Provision of information and signposting with no opinions or judgements offered.	Agreed
I would expect Manx Care Advice and Liaison Service to be totally independent to Manx Government. As things stand at the moment if someone makes a complaint to Government all too often it is swept under the carpet or the complainant is given the run around. I also feel that a member of the public should be involved as an independent witness to the complaints procedures to ensure that these are handled fairly.	MCALS is part of Manx Care and provides someone to help and advise people with concerns on how to best raise their concerns with the relevant service. Independent advice from people outside of the Government will be provided through the independent advocacy services. Independent advocates can attend meetings with complainants to support them and ensure that the complainant is listened to.
Defined pathway showing clear support mechanisms available to the complainant. As a lay person you were handed a form with no guidance at all. The individual has to seek out bodies that can help put together the complaint. Therefore one was so exasperated with the procedure or lack of they just simply give up!	Agreed MCALS can help you to access and communicate with the complaints team.
Full support to discuss the issue and to advise if I was or not being too critical	Agreed MCALS would be happy to discuss issues with you.

Understanding on what do to, who to contact, what the process is, how long it should take, who to follow up with if no response or unsatisfactory response	Agreed MCALs will help to access the complaints process and would be able to explain the process to be followed.
Honesty. Transparency. Timeliness. Useful signposting. Trustfulness. Empathy. Follow-up. Respect.	Agreed
I would expect to be told how to make a complaint, what the process involves and how long it might take.	Agreed
Empathy, openness, honesty, a willingness to pass on for investigation within a reasonable timescale and provide an honest response (even if it isn't quite what I'd like to hear!)	Agreed
I would expect acknowledgement of my compliant and also a quick resolution.	This would be for the complaints team to do but MCALS could signpost people to the complaints team and any relevant forms etc.
I would hope that it would provide a strong voice for patients and carers in relation to any issues arising from their treatment. I would also expect that the service would able to assist the public with navigating their care should it be affected by the pressures being faced by the Health Service caused by the coronavirus (COVID-19) outbreak.	Agreed, MCALS is a confidential help and advice service run by Manx Care that aims to improve patient and service user experiences by helping to navigate their care and sorting out any problems quickly.
An explanation, and an apology.	Explanations and apologies would be offered by MCALS; however, if the person wanted to make a formal complaint then MCALS staff would provide advice on that process.
1. A comprehensive guidance booklet containing all available options. 2. A dedicated point of contact with a senior member of Manx Care staff. 3. For those that need it, assistance through the process from start to finish.	1. This would be provided by the Department under the proposal that they should provide written advice and guidance on complaints and available options, help and support. 2. MCALS would provide a dedicated point of contact in relation to issues raised and would approach the care provider to ensure that communication is improved. 3. Such assistance would be provided by the independent advocacy service.
Sensitivity and professionalism. Clear and simple/easily understood advice. Accessible service. Liaison between the service user and the service.	Agreed
to be taken seriously and not dismissed as a trouble maker as has happened prior to Manx care being established	Agreed
I would expect a gentle, courteous and kind response that was efficient and compassionate. They would listen and help direct me to the next steps. They would be calm and reassuring.	Agreed

Advocacy could be part of the team to stop duplication. Independence from Manx Care to ensure public concerns are listened to. From personal experience PST do not investigate thoroughly and the complainant is left feeling PST are only there to protect their own, not the patient. PST should not be based in the hospital, they should be in a separate office.	There are different roles for MCALS and advocacy which will be explained by the Department's guidance document. MCALS is an internally operated service. The benefits of this are that MCALS staff know who to contact and where to find the necessary information to be able to help people address concerns quickly and simply. It is important that advocacy services are operated independently to Manx Care. If people are unhappy with the investigation completed by the complaints team, the complaint can be escalated to the proposed Ombudsman body for a review into how the complaint has been handled.
The issues, in general, come from miscommunication or information not relayed i.e. RISKS and BENEFITS of treatments. Often patients in difficulties with life-threatening diseases do not have time to consider options due to fear - fear of life loss, fear of diagnosis and treatment and fear of upsetting the doctor etc. - providing the treatment. People make decisions in situations of pain , fear that they would not normally make if they were not in this situation I think that MCALS could have another role before a complaint arises. They should be able to help and guide a patient through treatment if treatment is not understood. There should be a service whereby the patient can discuss treatment options and a place where someone can liaise between the patient and the practitioner. Often if we can improve communication care, time frames - patients, in general, accept this. If we look at MCALS process of advice and liaison in terms of complaints - they should be able to offer advice, guide the patient through the complaints procedure and ensure that all Facts of the case is disclosed. They should provide a timeframe for disclosure and be an IMPARTIAL < TRUSTED BODY that the patient and practitioner can disclose too They should be educated in a process and have some clinical knowledge to ask for the correct information and ask the correct questions to the practitioners. They need to be skilled in clinical process	MCALS is a confidential help and advice service run by Manx Care that aims to improve patient and service user experiences by helping to sort problems out quickly, providing advice and pointing people in the right direction to get the help they need. They do have a role in relation to helping people before complaints arise and their help in opening communication channels between care providers and service users should help to reduce the number of complaints. Your comments have been passed to MCALS for consideration of the additional services that it may be able to offer after the trial period.
A firm response or meeting preferably to discuss the matter, with a person who is qualified to deal with the complaint.	This would be a matter for the complaints team rather than MCALS.
I would expect a simple, clearly worded leaflet explaining how to go about lodging my complaint.	Agreed, it is necessary that this is provided.
Information on how to complain and advice on complaints procedure whilst complaint ongoing	Agreed
Listen to the complainant and seek to respond to the points raised. Past experience is that complaints are handled by using civil service dialogue, are condescending and seek to avoid blame and change outcome.	Agreed

Details about how to complain to the GMC or UK regulatory body which has authority to imposed sanctions directly on the responsible health care personnel	This is not within the remit of MCALS. However the proposals within the Regulations are that the service provider must
Acknowledgement that my complaint has been received and will be dealt with.	An acknowledgement is required within 5 days under the draft Regulations.
It would be the expectation that they would be able to provide advice and reassurance whilst taking the complaint seriously. It should also be expected that the issue be escalated to the correct departments dependent on severity of the complaint.	MCALS wouldn't deal with a formal complaint but they would listen to issues raised and contact the relevant department to help address concerns. MCALS will help people to understand their options and offer reassurance to people that making a complaint is sometimes the right way forward and won't affect their care. In those cases, people will be given advice on how to make a complaint.
To be heard To be provided with access to all medical notes and record if required To have answers provided to reasonable questions so you don't necessarily need to make a complaint. For Manx Care to be honest and upfront if things do go wrong.	MCALS staff work to open communication channels between the public and the care providers to help resolve issues and stop them escalating into complaints. MCALS cannot access or provide medical notes and records but would provide advice on how to contact the medical records team to be able to access records through the correct process.
Empathetic listening Information and signposting Follow up to any agreed actions	Agreed, this is part of the current MCALS service.

Within the responses received, there were 7 main elements related to the following themes:

1	Signposting, general guidance and information	(26.9%)
2	To listen, compassion, honesty, reassurance	(26.9%)
3	Strong communication and acknowledgement	(13.5%)
4	Accessibility, ease of use and access to personal information	(11.5%)
5	Professional advocacy and advice	(9.6%)
6	Independence from Government	(7.7%)
7	Accountability and/or apology	(5.7%)

Q.1.3 What services should the Manx Care independent advocacy service provide?	
You Told Us:	**DHSC Response:**
Providing full access and an ability to investigate	This is not the role of an advocacy service. This service should be offered by the complaints manager (or their team).
Support to those families with complaints against Manx care looking towards solutions to those issues	Agreed
An independent advocate for those who cannot manage on their own; to allow for the complainant to bring their own advocate or personal aid to speak for them if necessary; ease of access for meetings and to helpful personnel to manage the complaint.	Agreed - this would be within scope of an advocacy service.

Someone to talk to about complaints and how they are actually dealt with if at all	Agreed, this could be raised with an advocacy service or MCALS.
To facilitate letter writing for people who have difficulty articulating a concern	Agreed - this would be within scope of an advocacy service.
An update, support with how you are expected to trust the hospital after severe wrong doing. I was told whilst I had a complaint unanswered that I was scheduled for surgery with the same surgeon, by the complaints team, with no acknowledgement of how ludicrous that was.	This could be raised with MCALS.
Assistance and support in gathering information, advising on options, assistance filing complaint and dealing with enquiries and correspondence. Support and advocacy.	Agreed - this would be within scope of an advocacy service.
Face to face meeting Plain English communication	Agreed
Any that are needed for physical and mental health	Agreed
Explanation of d dinner systems pathway through jargon Named point contact Continuity	Noted.
Liaison with any consultants. Provide multidisciplinary service. If you currently have more than one consultant there's no inter action currently. Which would be invaluable	MCALS staff work to open communication channels between the public and the care providers to help resolve issues - this could include ensuring that service areas are interacting with each other for the benefit of the service user.
Already answered.	None
How is independent advice to be guaranteed? Advisors should have experience in complaints handling and should have easy access to independent medical and legal expertise. An ability to make an initial assessment on whether a complaint represents a serious cause for concern is essential. Minor issues can often be resolved with simple explanation rather than formal complaint. Advisors should be willing to act on the complainants behalf to present the complaint in a logical manner using verifiable evidence where possible. They should ensure that the complainant receives all relevant information and can understand all explanations provided by DHSC staff. They should also ensure that, when remedial action is needed, the complainant is informed and given opportunity to express an opinion. This would be easy if the complaints process was fair and transparent - it is not (yet).	It is intended that in future Manx Care will contract with an independent advocacy provider so that the service is offered by a body separate to Manx Care not by staff working for Manx Care. Agreed that an advocate would be able to support a person in making a complaint and ensure that the process was followed correctly, standing up for the complainant's rights.
I feel that Manx Care should look be looking at all aspects of Social Care on the island and support everyone who has experienced problems within the NHS services.	Agreed

Obviously an Advocate expert who has medical knowledge and understands the 'language' of the medical world In particular explaining medical reports in a way that the patient understands	Agreed
It should be prepared to stand up for the patient AGAINST the organisation if necessary.	Agreed
Support to individuals who perhaps can't raise concerns for themselves. A listening service for service users across the island with the ability to pass on concerns to the relevant area of Manx Care	Agreed.
Help with health-related questions Help resolve concerns or problems when using IOM health services Tell you how to get more involved in your own healthcare Give you information about: Manx Care Manx Care etc. complaints procedure, including how to get independent help if you want to make a complaint Support groups outside the IOM health services Help to improve IOM health services by listening to concerns and suggestions.	This would be the role of MCALS
Help, advice, and support.	Agree
1. Advice on the full range of options available to Health Service complainants 2. Advice on the availability of legal aid (where appropriate) 3. Advice on what role the Coroner of Inquests might have if the complaint concerns a death	MCALS can provide advice about services and options in relation to how to make a complaint.
- assistance with completion of forms and letters/emails - attendance at meetings between the complainant and the respondent to support the complainant, ensure fairness, witness what is said etc. - guide the complainant through processes - provide the complainant with reminders of approaching deadlines as appropriate	Agreed
should fully investigate all complaints and if necessary take legal action against civil servants who fail to adequately fulfil their legal obligations rather than bury them as was the common practice of the department prior to the establishment of Manx care	The Department is committed to ensure lessons continue to be learned from previous complaints, this includes matters relating to performance.
These should be broad enough to encompass all users of Health and Social Care services, with special reference to the most vulnerable (those with limited education, literacy, capacity and communication problems, for example).	Agreed

Manx Care independent advocacy service should provide email and telephone. A public office/drop in centre should be provided, at the very least meetings. A timely annual report on the work undertaken during the year, achievements and how they demonstrate independence. This report should be independent of DHSC in the same way the Tynwald Ombudsman reports directly to Tynwald. This was agreed by Tynwald 15 years ago in 33/06 (recommendation 1a) and it appears there is an attempt to delay again despite having 6 months to implement per the Tynwald vote in April 2021 ? This needs to be addressed by November 2021.	Noted - your comments will be provided to Manx Care for consideration in relation to the service specification for the independent advocacy service.
I like this section 1. Advice on Protocols and guidelines for specific treatments 2. Audit the patient pathways 3. Independent Trusted body to review the chronology 4. They should be able to liaise between patient and practitioner in an open, positive manner	Noted.
One with experience qualified and responsive staff	Noted
Once a complaint has been logged, if, and only if, a member of the medical team from the Department being complained about can't help the complainant then, and only then, an advocacy service takes on the complaint.	Independent advocates are people who can speak up on behalf of others. Especially those people who find it difficult to ask questions or raise issues with your care provider. In the context of complaints, they can help the complainant to understand the complaint process, talk to them about how they feel about their care and help them to stand up for their rights. They can write letters on behalf of complainants and attend meetings with them Advocates are independent of Government, social services and the NHS so would not take on the investigation of a complaint.
Support during complaints procedure and named person to attend any meetings. Mediation service if there is no resolution. Advocacy service could also be used to chase up if there are any delays in complaints procedure	Agreed
Services should be fast, 10 working days to respond. Responses should be proactive. They should be non-judgemental and "can do". Services should be face to face. (Online only is discriminatory). Legal options / opinion should be available. Users of the service should also be educated as part of the process as to the consequences of their actions. The service should also have confidence of the service providers and staff that it is independent, professional and exemplary.	Noted

Referral to regulatory body. Ability to arrange immediate alternative care for a patient in the event of a complaint against a specific health care employee.	Referral to a regulatory body is an area that the service provider must consider as part of an investigation of a complaint under the proposed Regulations. The Independent Advocacy Service will in future be provided independently of Manx Care so it will not have the ability to arrange any care services; however, if someone felt that alternative care was required then the Independent Advocacy Service could help that person speak up and ensure that their rights are heard and acted upon.
How can it be independent if it is 'Manx Care' Independent Advocacy?! This service should be provided by the DHSC as should a division to investigate serious events and complaints. Manx Care cannot guarantee impartiality when incidents are investigated by their own staff. Furthermore, staff currently carry out investigations in addition to their existing workloads. How then can they find time to thoroughly review a complaint or event and produce a comprehensive response to address all aspects of the complaint? I would expect more than a flimsy two page report if I had felt strongly enough to complain in the first place.	It is planned that in future the Department will require Manx Care to set out a service specification and go out to tender for an independent service.
An open and transparent service for service users as to how complaints will be dealt with moving forward, explaining the process and maintaining contact with the complainant during each step. Whilst keeping an open door policy for complainant's and ensuring confidentiality to provide reassurance.	This would be offered by MCALS rather than an independent advocacy service.
Assistance Advice Support Need to insure they were independent in giving any assistance.	Agreed
See above	None

Within the responses received, there were 7 main elements related to the following themes:

1	Extra support for vulnerable service users	(19%)
2	General assistance and support with making complaints	(19%)
3	Fully independent from DHSC and Manx Care	(16.7%)
4	Employees to have specialist legal and or/medical knowledge	(11.9%)
5	Face to face meetings, single point of contact	(9.5%)
6	Cover all aspects of health and social care services	(7.1%)
7	Liaise with service providers and users	(7.1%)

Q.1.5 What do you think are the best ways to provide advice, information and guidance to service users?	
You Told Us:	**DHSC Response:**
I think different people need different options. Simple prefer information on the web, some information in writing and others will need a personal contact. I think the option of a personal contact, person to speak to it's a great importance	Thank you for your comments. The Department will provide a wide range of advice, information and guidance communication options, including the ability to speak to someone face to face.
Online and printed	
Listening and helping them	
As many as possible, paper based in hospital, GPs practices, government buildings, website, Facebook, whatever makes it easier for service users and patients and carers really	
Every way available: printed, voice/recording; via IT/computers; large print sizes; braille; via an advocate to explain things; whatever method it takes. Try asking the person concerned.	
Leaflets readily available in all departments	
A person that you can sit and speak to who can also help to complete the relevant information.	
Leaflets, web site, face to face.	
Website Leaflets Presence at events Through local hubs	
Put it on the appointment letter Have a poster or two up in departments	
Face to face, email, and phone. Any way the person feels comfortable	
Prompt support at appropriate time Reassurance that inviting care not compromised	
Apart from clear. Easy to understand booklets. There has to be a person. Who you can interact with right throughout the process	
Leaflets in medical practices. Hospital patients should be given similar on admission. Easy, brief, and not reams of literature. E mail address and telephone no. to enable quick access to helps and advice	

The best way for providing information, guidance to service users is by being firstly being honest, secondly that any information be set out in plain English instead of the present government jargon which confuses people. To also understand that there are people who do not know anything about computers and that should be taken into consideration when supplying information.	
Step by step pathway for the individual to move through what can be an extremely stressful time in their lives with their loved ones in hospital.	
Information page on the Internet Flow diagrams Available to speak to someone who fully understands the process	
Whatever medium is best for the person. Choice.	
Face to face with confirmatory paperwork would be best - so that the complainant only has to tell their story once initially.	
Through all mediums; paper leaflets, written documents (e.g. appointment/discharge letters), online through websites, telephone contact and through social media	
using social media holding dropping sessions posters flyers hand out in GP surgeries, libraries, bus station	
Clearly written simple guidelines published on a standalone website with full contact details if further information is required. Information should also be provided in other languages.	
1. Guidance booklets available at all points of public contact 2. On line user friendly advice and guidance 3. Advice centre within the hospital and at DHSC offices	
By methods that the individual service user prefers - flexibility to provide via telephone, email, letter, in person, enlarged text, braille etc. Simple language. Sensitive and professional.	
Engage face to face with service users to properly assess both their needs and the possible failures of the service to meet the service users' needs and fulfil the department's legal obligations under current legislation	

Leaflets and phone line are useful but an open office somewhere accessible where service users can actually talk to a person would be ideal. Personal accessibility is crucial for vulnerable people.	
Re Q 1.4 above. Yes, with accountability for failure (no comment box provided) re Q1.5 By whatever method the user thinks appropriate to ensure DHSC are complying with equality and disability laws. Flexibility in communication, not put it in writing and no it's not our policy to meet you.	
1. Written - patient Complaints procedure 2. Website 3. Dept. of Health website Encourage every dept. to send a "CORE MESSAGE OUT" We are here to help, If you don't understand the treatment, have concerns please ASK!!!!!	
With a leaflet or information on social media and posters in places where people go.	
Face to face, with a written action plan personalised to the individual circumstances.	
Follow the guidance and best practice of regulatory bodies in the UK. Treat all complaints seriously and communicate this to the patient. Be open and honest. Recommend patient request access to their medical records immediately.	
Enclose leaflets (or links to websites) with outpatient appointment letters.	
Information and the route a complaint makes should be made available to the public to exhibit transparency across the service by way of using local media; updates on Manx Care social media platforms; leaflets in all Manx Care departments; updates and information in all post offices and pharmacies across the island.	
Awareness when you register or use a service, where to get further information could be included with appointment letters/emails. Wide variety of communication channels including posters, social media and a campaign when launched so people are aware of their rights and the service provided. Also ensure information is accessible to all service users.	

Website Posters in shared spaces Include contact details in appointment letters	Thank you for your comments. The Department will provide a wide range of advice, information and guidance communication options, including the ability to speak to someone face to face.
A dedicated role, someone of Nursing/ care background.	Noted - this would not be offered by the Department but is offered by MCALS.
As above. An urgent change of attitude from management is required to actively consider the merits of a complaint rather than adopt a defensive and condescending response to complaint. Complete records must be offered at an early stage to enable the complainant to make a comprehensively considered complaint. The current hospital complaints booklet provides information, but is not provided in all locations. Social services complaints process is not fit for purpose - I am currently advising on a complaint against Adult Social Care which has not been resolved after more than three years - unacceptable. There should be a single complaints process common to all departments. Public confidence in the current complaints process is low. In order to address this more use should be made of expert external review and a contract with a reliable UK service e.g. Niche would be cost effective.	Noted
Exactly as mentioned above.	Thank you for your response.
Through MCALS	MCALs will be able to help people access the complaints process. The Department will also provide a wide range of advice, information and guidance communication options, including the ability to speak to someone face to face.

Within the responses received, there were 8 main elements related to the following themes:

1	Paper and online written information	(45.8%)
2	Face to face communication and meetings	(25%)
3	Email and telephone communication	(14.6%)
4	Information printed on appointment/discharge letters	(12.5%)
5	Promotion on social media	(12.5%)
6	Accessible information e.g. braille	(10.4%)
7	Leaflets/posters in health and social care settings	(10.4%)
8	Promotion in community hubs	(8.3%)

Q.2.1 Do you have any comments on the proposed two stage process for complaints?	
You Told Us:	**DHSC Response:**

This looks sensible to me	Noted
No	None
I think issues raised and resolved with staff members should be noted and considered by Manx care as if it kept happening that way where staff members only put it that far with same complaint and may have been temporarily resolved with staff then it could still be an issue so needs looking into	It is agreed that issues raised with staff should will be recorded as a concern/enquiry that could then be reviewed and changed to a complaint if there are further issues that needs looking into.
Like the UK - it seems very high-handed and actually appears to pre-assume that the complainant is in the wrong. I find it prejudicial. It is certainly prejudiced against the complainant by the wording itself.	Your comment has been noted, but it is unclear why you feel this way.
Are staff going to be able to deal with complaints at the time as I have found they are always short staffed and more than half are not interested	If issues or complaints are not dealt with in the 3 days allowed then they would automatically become a formal complaints to be investigated and responded to in writing.
Not if they are carried out as layer out. At the moment a complaint is not investigated it is just given to the person concerned and they give an answer. THIS IS NOT AN INVESTIGATION.	The regulations require an investigation to be carried out by the service provider.
Yes, when I made a complaint it took more than 20 days without an acknowledgement until I chased that there was a delay in signing it off. So at present, the elements of it that are in place re timescales don't work.	It is noted that there are currently issues with the complaints process. The Department plans to monitor adherence with the timescales as part of its assurance framework in relation to how Manx Care is handling complaints.
It must be kept simple. Government legal service craftsmen need to write in plain English. There need to be template forms and procedures for the complainant and service provider. There must be a full written record. The managers of service providers need training on how to identify what is a complaint, how to resolve it successfully and how to record the investigation, outcome and how to learn and improve.	Thank you for your comments. We agree with these points and all are considered within the scope of Regulations.
Looks fine	Noted

Stage 1 needs to be handled by someone who isn't out to show they are the 'big man'. Stage 1 shouldn't be handled by someone who has already made their mind up before they have even spoken to the staff. Stage 1 shouldn't assume staff are guilty until proven otherwise Stage 1 shouldn't be handled by someone who will go out of their way to try and get the staff member struck off. Stage 1 should not take months and months and months placing at times unbearable stress on staff members involved. Stage 1 should have clear communication and follow the procedures as set out. Stage 1 reviewers who have shown to be incompetent at reviewing and assessing a complaint should be educated as to the proper procedure. Staff should not be terrified of doing their everyday job for the fear of someone in management out to get them sacked. Anyone undertaking Stage 1 reviews should be trained, assessed as competent, and audited regularly.	Thank you for your comments. The culture with the organisation cannot be changed by legislation but we are working with the workforce and culture project team within the Heath and Care Transformation Programme to ensure that issues such as those that have been highlighted by your response are addressed. The workforce and culture project is focussed on developing and implementing a fit for purpose organisational model that removes the long-standing cultural barriers that have impeded the growth of integrated and collaborative working in the Department, now Manx Care. As well as improving organisational culture, this project will set out to recalibrate and build on efforts relating to organisational and workforce development that have already been developed or taken place. There are work streams in progress which focus on the values of Manx Care as an organisation, on creating psychological safety in the workplace, creating a learning culture, recognition activities and wellbeing opportunities for Manx Care employees. All of the elements within the Workforce & Culture five year plan will contribute to creating a positive working environment. The key to success is to embed this across the organisation over the course of the project and ensure that it is sustainable for the future.
in either stage the dept. dealing with it should be made of independent people, not people working or occasionally working in the depts.	The first stage of investigating a complaint should be carried out by someone working for the service provider and in a positon to find out the necessary information and with the ability to ensure that changes are made to put right any issues identified. The second stage is for an independent review of the complaint, if the person is unhappy with the response provided or it is taking too long to get a response.
No	None
As long as the department is willingly and readily to accept any recommended changes	Agreed
Having already used the existing process and found it lengthy, I can see no real difference in what is proposed.	Thank you for your comments. There are changes within the timescales set out in the Regulations to require the complaints process to be completed more quickly. Going forward the Department will be monitoring adherence with the timescales as part of its assurance framework in relation to how Manx Care is handling complaints.

The IRB cannot be considered to be independent or expert. It comprises a variety of individuals of different backgrounds. They largely take their advice from the departments who may well be the subject of complaint. The complexities of some complaints are likely to be beyond the understanding of these individuals on occasion. Where resolution is not achieved following a written complaints management response and face to face meeting, the appropriate next step is to commission an expert external review.	Changes to the membership of the IRB were proposed within the consultation paper and will be developed further by the introduction of the Ombudsman body brought in by the new Regulations. The Ombudsman body members will be required to have relevant experience in health, social care, dispute resolution, law or administrative justice. In addition, further expert advice will be able to be sought if necessary in relation to a specific, complex, complaint.
I feel that the process for complaints is rather long drawn out and open to delaying the process. As I stated previously complaints at present are either brushed under the carpet or are ignored so complainants must have guarantees from Manx Care that they will be treated fairly.	Under the revised Regulations complaints must be acknowledged by Manx Care within 5 working days and, in the majority of cases, responded to within 20 working days. If there is a specific reason why a response cannot be issued within 20 working days (for example, due to the complexity of the complaint) then Manx Care will be able to notify the complainant of the additional time needed to consider the complaint and prepare a response. If a complaint is not completed by Manx Care within 3 months, it can be referred to the Ombudsman body.
I've seen posters for complainants displayed at Broadgreen hospital. The public need to be more aware of how to navigate their way through from a minor to major problem	Thank you for your comments. The Regulations required action to be taken to publicise complaints arrangements. This will be supplemented by having MCALS within Manx Care to provide advice to people who need it and by the Department setting out additional guidance so that people are aware of all options in relation to complaints.
Yes The ambulance service works on a rolling 2 days and 2 nights. 4 days off. 3 days is too short a window	If complaints cannot be responded to by front line staff within the 3 day timescale, they will automatically become a formal complaints to be investigated and responded to in writing.
No	None
I think as compressed a process as possible is a good idea. I didn't even look at Annex 1 because it seems so cumbersome. I prefer the term concern to complaint or even dissatisfaction, disagreement, difference of opinion, constructive criticism etc. I find that most people just want to be heard rather than be seen to be complaining, and usually apologised to if they have been treated unfairly.	Agreed, the 3 day allowance for concerns to be raised is for that reason. If the concern is able to be dealt with there and then, the person is heard and apologised to then the concern will not become a formal complaint.
This seems to fit in well with expectations. The IRB should include have a team of people available as a member of whichever discipline is being 'complained' about to include an independent professional viewpoint	Agreed
if it works it will be fantastic	Agreed

All complaints should be handled in a positive way - they offer an opportunity for improvements in the service being offered. Staff handling complaints need to fully understand and agree the key issues to be considered, what impact it has had and what outcomes are being sought before carrying out an investigation. Depending on the complexity of the complaint and the work that is likely to be involved in carrying out the investigation, the complaint handler should discuss with the person a realistic timeframe for how long it will take and explain how the investigation will take place. Following the investigation the complaint handler should explain why things went wrong and identify suitable ways to put things right. They should also make sure the apologies and explanations they give are meaningful, sincere, and openly reflect the impact on the individual or individuals concerned. Staff should feel empowered to identify suitable ways to put things right for people who raise a complaint.	Agreed - this is certainly the intention. The Department will use its assurance framework to ensure that Manx Care is following the statutory process and learning from complaints received.
Currently the process in the Isle of Man is completely useless and takes far too long. The proposed process is not much better and the Ombudsman system in the UK frequently fails and has little or no right of appeal. The current parliamentary ombudsman scheme in the Isle of Man has already failed with cases taking in excess of two years and still unresolved. The fact is that the current complaints process is being used against complainants to simply wear them down so that they give up.	Thank you for your response. Following the consultation further changes will be made to the Regulations with the intention of speeding up the process for individuals (if a complaint has not been addressed by the service provider within 3 months then it will be able to be escalated to the Ombudsman body for review).
Stage 1 allows for the complainant to make a complaint within 12 months of becoming aware of the problem. Stage 2 allows for the complainant to request a review also within 12 months of becoming aware of the problem. If left as it is then any complainant making a complaint in the 12th month is highly unlikely to have any right to request a review due to the lateness of the original complaint being submitted. Either; - the time limit for submitting a complaint at stage 1 is too long, - the time limit for requesting a review is too short, or - the time limit for requesting a review should be based on a length of time from the date of decision of formal response at stage 1 and include a maximum length of time from when the complainant became aware of the problem, whichever is arrived at first	Thank you for your comments. The Regulations will be amended to allow a complaint to be made under stage 2 within 12 months of becoming aware of the problem or within 6 months of the date of decision of formal response at stage 1, whichever is longer.
if this proposed process is brought into action and properly managed it will resolve the historic issues of isle of man government and the department of health failing to resolve serious complaints in regard to the failures of the department and government to meet their legal obligations to service users	Noted.
No.	None

Stage 1. Orally needs a threshold to ensure a serious complaint is logged even if it was oral. Serious oral complaints would be accusation of physical or mental abuse on ward. The ward sister coming along asking for an official form to be signed is likely to meet with resistance if the patient is still on the ward. For example. My mother was verbally abused, the Sister intervened and the staff member came back in the early hours to have "another go". My elderly, terminally ill mum was too frightened to complain again. Another example would repeated calls regarding delayed cancer scans Stage 2. Have you removed the right to a review by a second convenor which is specifically contrary to the 2006 vote? Second convenor independent review should form part of the IRB procedure by regulation. There is evidence that a second convenor review system is working, they don't always agree with the first convenor. If the IRB were qualified Ombudsman or medically with a professional regulator then fair enough, but the IRB are lay people, unqualified so you need the double check of the second convenor at the moment. The IRB have not been proactive for many years and have let their organisation stagnate. Therefore a separate qualified Ombudsman should be appointed immediately, Tynwald Ombudsman to review for maladministration now (November 2021) with truly independent adjudicator first quarter next year in accordance with the vote of Tynwald 15 years ago. I have made comment on paper two of this consultation but thought it important to note it here.	Oral complaints or issues raised should be logged by staff on the incident reporting system; however, this will be left for inclusion within the complaints handling procedures rather than being a requirement of the Regulations. If the oral complaint is not resolved within 3 working days then it would automatically become a formal complaint to be investigated (even if it was made orally). The detailed process for the review by the Ombudsman body will be required to be set out in a published document by the Ombudsman body in compliance with the revisions to the draft Regulations. Your suggestion for the TCA to have a reviewing role was considered but it was determined that to add another review mechanism would undermine the decisions of the Ombudsman body.
The IRB is not fit for practice or Purpose it needs to be INDEPENDENT It needs to have EXPERT MEDICAL INPUT It needs to be able to AUDIT and understand when essential information is MISSING It needs to have a 3 month TIMELINE to RESOLVE ISSUES It needs powers to MAKE the practitioners participate in the Procedure	Following consultation, it has been determined that the proposed IRB will be replaced by an Ombudsman body. This Ombudsman body will be independent of those providing the services on which it will review complaints. In future it is planned to make this Ombudsman totally independent of the health and social care system. It will be made up of experienced people and will be able to access further expert medical advice, if necessary. It is proposed that the Ombudsman body should have a 20 day timeframe for deciding how the complaint should be handled (and notifying that to the complainant) and then 6 months to prepare a report. Any recommendations made in that report and action to be taken will be made public.
It at this stage	Noted
No	None
Good proposal for 2 stage process. People who raise a complaint orally will need to be informed that it will not be logged as a complaint unless in writing. Although good that it should be resolved in 3 days	Thank you for your comments. Oral complaints should be logged as issues in the incident reporting system, if they are not able to be resolved within 3 days they will then be upgraded to formal complaints to be full investigated and reported on.
Nothing new here. This has been happening for years in industry	Noted

6 months is too long and torturous for both parties	Thank you for your comment. It is proposed that the 6 month timeframe for being able to refer the complaint to the newly proposed Ombudsman body is to be reduced to 3 months.
Complainant should also be provided with materials provided to IRB by Manx Care at the same time they are provided, if they request such access. If you choose to make an oral complaint first but not instigate the complaint process, it should be also possible go back and use this as the date of the complaint if necessary, if you then go on to make a formal complaint and would be out of time, if you can demonstrate you have followed up on the oral complaint. You should also be made aware when making an oral complaint of the complaint process and that this oral complaint doesn't form part of it.	Agreed, an oral complaint that is not resolved to the complainant's satisfaction with 3 working days will be treated as a formal complaint.
3 days is too short to enable verbal resolution thus avoiding a formal complaint. What if the staff member is ill or on holiday?	It is considered that 3 days is appropriate for an issue raised informally to be resolved. If it takes longer than this then it should be followed up and responded to as a formal complaint.

Within the responses received, there were 5 main elements related to the following themes:

1 Supports the proposals (20%)
2 Complaints about current process (15.6%)
3 Disapproval of proposed new process (6.7%)
4 Concerns regarding staffing and timescales (6.7%)
5 Suggestions for the process: (33.3%)

- Simple language/accessibility
- Logging all issues and incidents
- Objectivity and independence
- Reduction to proposed timescales
- Easy to access information and advice

Q.2.2 Do you have any comments on the proposed transition period for providers of health and social care services other than Manx Care?	
You Told Us:	**DHSC Response:**
Looks reasonable and pragmatic	Noted
No	None
Good idea	Noted
Surely any reasonably intelligent manager could comply with these regulations immediately. It is not rocket science.	Noted
No not if the times are adhered to	None
No comment	None

No	None
That seems fair	Noted
None	None
The new draft proposals are very similar to current procedures with some extra detail on responsibilities. It is the manner in which the process is implemented that needs scrutiny. It is unusual for the process detailed in the booklet to be followed. There are often unexplained delays in sending a written response to a complaint and difficulties in arranging meetings. Requests for copies of medical records are met with delays of two months or more. Sometimes these are offered in cd form which are impossible to access on a home computer. Any transition period should be used to monitor the way in which complaints are managed. Why is this not already happening?	The Department will have a role in assuring that Manx Care complies with the proposed Regulations.
No Comment	None
Should not be an issue if rolled out across the organisation in a timely manner so every provider knows exactly the correct procedures immediately	Noted
No	None
This seems quite fair	Noted
ok	None
It is imperative that complaints relating to all aspects of health or social care are handled quickly and fairly. The transition arrangements proposed seem reasonable given the structure and complexity of the organisations involved. However it would be sensible to ensure that no complaints made during the transition period were left unresolved.	Noted
The proposed transition is far too slow. Complaints handling is not rocket science just decent treatment of individuals who have sometimes suffered very badly. The change needs to be immediate even if the regulations have to follow after the event.	Manx Care is already making improvements to its complaints arrangements and these improvements are aligned to the proposals set out in the consultation. It is anticipated that the changes will be made before the Regulations are implemented to give them a statutory basis.
Given the appalling state of the management structure within the department of health as identified by the Michael's report I would hope that the process can be enacted within this time scale although I would not be surprised if the level of structural insufficiency identified during the process could significantly extend this process	Noted
A transition period of one year may be more effective for smaller organisations.	Your comments are noted. Further communications with all service providers is planned to ensure that they have as much notice as possible to implement the changes.

Yes far too long. The transformation team were given 6 months by Tynwald to rectify a relatively simple situation and the current proposals do not go far enough. There appears to a move to delay progress to suit management and this is not acceptable. The Department should start making public protection a priority and be transparent. The changes are not significant and can be dealt with very quickly. There appears to be a delay tactic and when public harm or worse death is at risk then these regulations should be implemented and effective November 2021. DHSC asked for 6 months in April and Tynwald agreed to 6 months. This should not be dragged out any longer.	The changes to be made by regulations are complex from a legislative point of view and could not be developed, publically consulted upon and made within 6 months. Work is continuing to bring them in as soon as possible.
They need to comply IMMEDIATELY They are Health Care professionals who Should NOT WANT complaints and therefore dealing with them swiftly, efficiently should be welcomed	It has been decided that the transition period for bringing in the Regulations will be 3 months after the Regulations have been approved by Tynwald (in October 2022). In order to do so, further engagement with service providers will be undertaken whilst the draft Regulations have been published awaiting Tynwald approval so that providers can begin to implement any necessary changes before the Regulations have been formally approved.
Totally agree	Noted
The transition period should be as short as possible because all the people are professionally trained staff who have had to make decisions every day of their working lives and are well aware of the implications involved.	It has been decided that the transition period for bringing in the Regulations will be 3 months after the Regulations have been approved by Tynwald (in October 2022). In order to do so, further engagement with service providers will be undertaken whilst the draft Regulations have been published awaiting Tynwald approval so that providers can begin to implement any necessary changes before the Regulations have been formally approved.
Seems fair	Noted
What does Sir Jonathon Michaels think of this?	Sir Jonathan Michael retains an advisory role on the Transformation Programme Board and so is kept updated and has an ability to comment on the proposals put forward by the Department.
That seems reasonable.	Noted
Is there a source of help and guidance for e.g. complaint managers to access?	An operational policy and procedure should be set out by all service providers as part of the implementation of the Regulations.

Within the responses received, there were 4 main elements related to the following themes:

1	Supportive of proposals	(35.3%)
2	Transition period is too long	(11.8%)
3	Transition period is not long enough	(2.9%)
4	Comments not related to transition period	(20.6%)

Q.3.1 Do you have any comments on the proposed changes to be made in relation to making a complaint and it being acknowledged?	
You Told Us:	**DHSC Response:**
No	None
No	None
Sounds a better system	Thank you for your feedback
No that seems reasonable. However - there should be the opportunity to object to the contact person handling the complaint. This is a small Island and the complainant should have a choice for many reasons, for example: they could be related; there may be a negative history between them.	Thank you for your comments. It is agreed that if there is a conflict of interest for the person handling the complaint this should be considered and someone else should investigate the complaint. This will not be set out within the Regulations but all Government employees are required to raise conflicts of interest in relation to the work that they do. A conflict of interest arises when a member of staff might reasonably be perceived by a member of the public to be likely to be biased, partial, or otherwise personally interested in the outcome of dealings between citizen, business or organisation and the Government. The test which should be applied in relation to a potential case of perceived bias is: "whether the ascertained relevant circumstances would lead a fair-minded and informed observer to conclude that there is a real possibility that the decision-maker was biased." The Department will issue guidance for complainants to let them know that they can request someone else handles the complaint if they feel that there is a conflict of interest.
No as long as this time scale is followed	Noted
no	None
This is a big improvement	Thank you for your feedback
Makes sense to be aligned to UK standards	Thank you for your feedback
as experience has shown myself, a complaint can be written or verbal and acknowledged but then can be ignored or forgotten	Thank you for your comment, which has been noted. The changes should mean that this cannot happen in future.
No	None
Again that seems fair	Thank you for your comment
Little change.	There are several changes proposed within these Regulations, including an extension to the timescales for making complaints and prescribed timescales for responses to complaints and for complaints to be referred for an independent review by an Ombudsman body. For the first time statutory requirements are being put in place for complaints about social care services to be addressed by Manx Care and providers that provide social care services on its behalf. The changes will also allow for a single integrated complaints policy to be created for all services provided by Manx Care making the process simpler for any potential complainants and for the staff to manage.

A potential complainant should be given rapid access to relevant medical records in order to present a coherent complaint. Without this, some details may be omitted or inaccurate and any request from the complaints manager for further detail or clarification would be inappropriate	There is already a standard process in place to be able to request access to medical records. The Department will issue guidance to help people navigate this process.
It states about patients complaints, what if the patient isn't capable of making a complaint? Does the main carer have the right to lodge a complaint on behalf of the patient?	Yes a representative will have this right and this is set out in the Regulations.
Best practice should be implemented asap	Thank you for your feedback.
No	None
Agree with the proposals; good to come in line with international and UK standards	Thank you for your comment.
think this would give a more realistic time frame	Thank you for your comment.
The timelines all seem reasonable.	Thank you for your comment.
I see no reason for following the process in England. This is just creating delay for the sake of it.	Noted.
Agree with 5 working days for acknowledging the complaint. However, shouldn't the time limit for resolving informally match this as well rather than being a 3 day limit as is currently proposed? For consistency and practical application reasons.	If the concern is resolved informally within 3 days then it would not become a formal complaint under the Regulations and require an acknowledgement or a response so it makes sense that this is a shorter date that the 5 days to acknowledge the complaint.
long overdue	Noted
No. It should be borne in mind that an acknowledgement letter may not be practical for some complainants (i.e., those who are illiterate or homeless). In these cases some other form of acknowledgement should be provided.	The Regulation wording has been amended in relation to the acknowledgement and response to allow for other communication methods to used, if necessary (with the consent or at the request of the complainant).
Yes part of the regulations should state that a meeting be offered in an attempt to resolve the complaint quickly. See my notes on the draft regulations.	Noted. As part of the investigation into the complaint, a complainant must be offered a meeting to discuss the complaint.
I think that is reasonable	Noted
There should be an acknowledgement that the complaint has been received	This is required within 5 days of receiving the complaint.
No.	None
No seems good	Noted
Complaints should be directed to those who can authorise change.	Agreed
How does this affect a minor's rights before and when they reach maturity?	A minor could make a complaint themselves or a representative could make a complaint on his/her behalf.

I do believe the timescale for the complainant should be extended to 12 months. In regard to responding to a complaint I think a two-step procedure could take place here with: 1. An initial official acknowledgement of the complaint received. (3 working days from initial contact) 2. After review an outlined response / apology regarding the complaint and provide a clear and concise outline of choices for the complainant as to how they would like to proceed using the systems in place (5 working days from step 1 being sent). People like to feel that they have some control and say regarding the situation. This provides the complainant with a sense of empowerment which keeps them engaged with the service, and provides them with a sense of trust of the service also. Allowing people choices on how they would like to proceed with any complaint also shows transparency of the service provider.	Noted; however, most respondents were in support of the proposals within the consultation paper so no change will be made to the process for acknowledging a complaint.
I think the timescale should be longer as if you were traumatised by what had happened you might not be in a position to complain within 12 months or have full awareness that you should. Whilst there might be a time limit in terms of what can be done, I don't think anyone should be deterred from having a complaint heard and investigated no matter what the time. It may if a significant amount of time has elapsed for another process to be followed but I feel there should be an option for this. Imagine if you hit a complaint over the time limit and it wasn't looks at but future issues could have been avoided if it was.	There is flexibility given to investigate a complaint made after the 12 month timescales if there are good reasons for not making a complaint within that timescales and the complaints manager feels that, despite the delay, it would still be possible to investigate.
Extending the time limit for making a complaint to 12 months would be much better. I wanted to complain about something, but by the time I'd built up the resolve to do so, the 6 month limit had passed.	Noted
Seems reasonable	Noted

Within the responses received, there were 5 main elements related to the following themes:

1	Supportive of the proposed changes	(30.2%)
2	Timescales	(16.2%)
3	How acknowledgements will be communicated	(11.6%)
4	Accessibility and representation for vulnerable service users	(7%)
5	Best practice to be pursued	(4.7%)
6	Not supportive of proposed changes	(4.7%)
7	Ease of access to personal medical records	(2.3%)

Q.4.1 Do you have any views on the suggestions to ensure that people dealing with complaints are experienced in doing so?	
You Told Us:	**DHSC Response:**
I do agree with the importance of training all staff in dealing with and handling complaints. I think the broad principles embodied within the act in the legislation the sound but I don't underestimate the scale of the task to embed them in the actions of all staff	Noted
No	None
Of course those dealing with complaint should be experienced and wanting to solve the issue this shouldn't just be a suggestion it should be happening	Agreed that this should be the case now. It will become a legal requirement under the proposed Regulations.
Don't be defensive, any issues me or my family have had in the past have always been met with a defensive attitude.	Noted, the implementation of the Regulations will need to be supported by an open and learning culture. Work is underway to address some of the cultural issues within Manx Care supported by the workforce and culture project, which is in place as part of the Heath and Care Transformation Programme to deliver on Sir Jonathan Michael's 25th recommendation. There are work streams in progress which focus on the values of Manx Care as an organisation, on creating psychological safety in the workplace, creating a learning culture, recognition activities and wellbeing opportunities for Manx Care employees. All of the elements within the Workforce & Culture five year plan will contribute to creating a positive working environment.
Everyone working in the service should be adequately prepared to deal with initial complaints. This should be a part of many of the jobs within the IOM Gov where workers have a face to face contact with the public. They do not need to be over-trained or over experienced. Just someone who is approachable, empathetic, has common sense and some basic knowledge of the right way and the wrong way to do things.	Noted. The proposals require all staff that interact with the public to be given a basic level of training to ensure that they understand the process to be followed in making a complaint and are able to help people that raise concerns.
Yes they should be fully trained and above all sympathetic to people's needs	Noted
People need specific training on how to deal with any health concerns	Noted
Yes, my complaint was handled poorly e.g. rescheduling me for surgery with the same surgeon with the complaint still outstanding. The people dealing with it were nice when I contacted them but were apparently oblivious to worry and stress caused by their inability to factor in practical implications of what they were suggesting	Whilst raising a complaint will not affect the care provided to individuals, it is noted that this situation would cause worry and stress. The Department will issue guidance to service providers to ask them to consider the practical implications associated with complaints.
Training in complaints handling is vital. It must become part of service provider culture	Agreed
Training and responsibility are important.	Agreed
See previous comment.	None

Training in different areas is essential, the law must also be understood and more importantly the person's complaint should be treated as unique, as each problem will be.	Agreed
Should welcome complaint as a process to the improve service or perception of same. Staff here often blame managers system politics plead busyness low morale Loose talk about how awful it is how nobody helps them how badly done to they are. Easily bribed and rewarded by sweets cakes gifts. No keep the swan swimming approach	Noted, it will become a requirement that complaints are welcomed and a just and learning culture is promoted. This will be supported by the work of the Workforce and Culture Project, which is in place as part of the Heath and Care Transformation Programme to deliver on Sir Jonathan Michael's 25th recommendation. There are work streams in progress which focus on the values of Manx Care as an organisation, on creating psychological safety in the workplace, creating a learning culture, recognition activities and wellbeing opportunities for Manx Care employees. All of the elements within the Workforce & Culture five year plan will contribute to creating a positive working environment.
It's only right that staff are trained to the required level for their role	Agreed
Is this a way of creating more managerial position within a Health Service already top heavy in its staffing.	There is no additional staffing being suggested within these proposals.
The consequences of drawing the wrong conclusion in these circumstances can have very serious implications for the complainant or the subject of complaint. This goes far beyond simply an administrative role in dealing with a complaint. An expert external review should be considered a normal step when resolution of a serious complaint is not readily achieved	Under these proposals when resolution of a complaint is not achieved by the service provider, the complaint can be referred to the Health and Social Care Ombudsman body, which will be made up of experienced members.
At present there is no one experience in the DHSC for handling complaints. If they are trained in handling complaints then let's hope that they treat everyone justly because at present the system does not work.	Noted, training is to become a mandatory requirement under the Regulations
I do not think that this is a role for an individual That person cannot possibly be Jack of all trades and I think one person should be selected depending upon their knowledge and expertise on the subject matter with fair representation and translation to the complainant	Noted
Proper training and Support and apathy	Noted
Funding for extra staff to deal with complaints may impact on employing enough staff to carry out good quality care in the first place however relevant people dealing with complaints certainly need to know what they are doing	Noted
No, just that they are indeed experienced and have ongoing updated training in doing so.	Noted
Yes, they should be experienced but should not lose sight of the fact they are dealing with humans, and the process should not be the priority.	Noted
Complaint handlers should be trained in how to manage these matters effectively	Agreed, this is the proposal

start the training of this staff as soon as possible and hopefully they have a robust clinical supervision	Agreed
There are many ways in which people can now learn how to deal with complaints. Anyone entrusted with complaint handling (including members of the IRB) should be expected to undertake relevant training and achieve an acceptable qualification. The UK NHS has online e-learning resources available to help staff gain qualifications. Guidance produced by NHS Choices and the Parliamentary and Health Services Ombudsman supports NHS staff in implementing the complaints procedure, and specifically requires all NHS staff to be appropriately trained to enable them to respond efficiently and effectively to feedback. There are other online resources available to non-professionals too.	It is agreed that there are a lot of resources available for people to learn and gain experience and it will be for individual service providers to decide what level of training is necessary for its staff.
They should have knowledge of the particular medical problem being complained about.	Noted
It is not necessarily the experience but the independence from the party being complained about. Currently, there are too many conflicting interests. Complaints handlers should be drawn from a pool of independent individuals or people working in different departments.	Thank you for your comments. It is agreed that if there is a conflict of interest for the person handling the complaint this should be considered and someone else should investigate the complaint. This will not be set out within the Regulations but all Government employees are required to raise conflicts of interest in relation to the work that they do. A conflict of interest arises when a member of staff might reasonably be perceived by a member of the public to be likely to be biased, partial, or otherwise personally interested in the outcome of dealings between citizen, business or organisation and the Government. The test which should be applied in relation to a potential case of perceived bias is: "whether the ascertained relevant circumstances would lead a fair-minded and informed observer to conclude that there is a real possibility that the decision-maker was biased." The Department will issue guidance for complainants to let them know that they can request someone else handles the complaint if they feel that there is a conflict of interest.

Within the responses received, there were 3 main elements related to the following themes:

1	Supportive of the proposals	(55.1%)
2	Concerns about staff culture and attitudes towards complainants	(16.3%)
3	Concerns regarding funding of proposed training	(8.2%)

Q.5.2 If you disagree, or have additional suggestions, please provide further comment.	
You Told Us:	**DHSC Response:**
External & independent oversight is required	Agreed, it is proposed that the Health and Social Care Ombudsman body will provide this external and independent oversight.
Where ever possible hold in person dialogue. Be open, transparent and honest as possible	Agreed, under the proposals a meeting must be offered to every complainant.
Should the complaint not be resolved, then a legal pathway should be the NEXT avenue to be sought	Noted, nothing in the proposals would stop legal action from being taken.
Yes but the current requirements are not even being met.	Noted, the Department now has a role in overseeing how Manx Care implements the new requirements and will require assurance information from Manx Care in relation to complaints handling.
But the complainant may be highly emotional and stressed by the situation so support should be provided at any meetings to them	Agreed.
As long as this is not another stick to beat the staff with and if the complaint is found to have no substance the staff member is supported	An additional section will be included within the Regulations focussing on support for staff members that are complained about, similar to what is required of service providers for staff that are involved in a duty of candour incident.
All best interest practices should be undertaken on the IOM.	Agreed
The coroner and police (as coroner's officers) should be more involved with hospital deaths where they involve complaints about the health service	Coroners have a specific role as independent judicial officers who investigate deaths reported to them. They will make whatever inquiries are necessary to find out the cause of death, this includes ordering a post-mortem examination, obtaining witness statements and medical records, or holding an inquest. Under the Coroners of Inquests Rules 1988: A coroner who believes that action should be taken to prevent the recurrence of fatalities similar to that in respect of which the inquest is being held may announce at the inquest that he is reporting the matter in writing to the person or authority who may have power to take such action, and he may report the matter accordingly. This would be sent to the DHSC or Manx Care to action as appropriate.
For a service user or their representative to threaten legal action implies that the department has failed to adequately manage the resolution of the complaint. Rather than await a private legal action the department and the service user or their representatives should automatically have access to a Government established independent arbitration service that has the capacity to examine every aspect of the complaint and make a judgement on the basis of their findings which is legally binding on both parties thus avoiding the cost and stress a legal action would occasion to all parties involved and increase trust in the system rather than undermine it through negative publicity	This has not been incorporated based on the legally binding and possibly 'unfair' position this introduces.

Yes, please see my notes on the actual regulations. In relation to the clause which potentially put onus on the complainant to provide technical information, the Complaints Manager should ensure (by regulation) that assistance is given to the complainant to provide further information. (I.e. how can you expect the public (as in my case) to review and comment complex medical records? How do the bereaved, elderly, depressed etc. do this without help? Equality issues? IT or literacy issues? "Relevant health or social care professional" has to be a clinician, i.e. doctor who can answer questions. For instance, a medical secretary is a "healthcare professional" but cannot answer questions on complex cancer tumours. Clinician was the term used by 33/06 15 years ago and it is disappointing that this has been generalised. This needs to be changed. The complainant needs to receive meaningful responses, not we are working on it and a promise of someday. Fixed timescales should be included in the letter to the complainant. A delay in one part of a complaint should not delay the whole complaint response.	Thank you for your response in relation to the Regulations which has been considered separately. The clause that you mention is not intended to put the onus on the complainant to provide technical information - medical records will be held by the service provider and so should not be requested from the complainant. This paragraph is included to cover circumstances where the complaint received is not clearly articulated and the complaints manager requires additional information in order to ensure that the questions to be investigated truly meet the priorities of the complainant. Healthcare professional has a specific meaning within the Healthcare Professionals Act 2014 and only includes registered professionals (across a range of medical disciplines) but would not include a medical secretary. Clinician is very health focussed and it has been generalised to include social care as well. It is agreed that meaningful reponses must be provided.
It is impossible almost to make a complaint legally on island unless you have a SMALL FORTUNE - that is WRONG. You should be able to Complain if you have a legal stance or not that is only fair Money stops patient pursuing complaints - I have witnessed this in practice Happy to discuss further Also if the patient had complained to the regulatory body in the UK is it fair to have 2 investigations going at the same time - CONFUSION. ONE PATHWAY!!!!!	Any person that has a complaint to make about a service provider will be able to make a complaint under the arrangements outlined within the Regulations and will be entitled to have it properly investigated and responded to. People may also want to make a complaint to a regulatory body, if they feel that a health or social care professional poses a risk to patients or service users or has failed to meet the standards expected by that regulatory body. These are 2 separate processes that will look at different issues in relation to the complaint. The Department will provide guidance for people thinking about making a complaint to help them to decide which route for raising the complaint would be most appropriate to get the result that the complainant wishes.
Regardless of any legal outcome, the internal health care investigation is an opportunity to demonstrate impartiality. Whether its findings subsequently become part of the legal evidence for the plaintiff should not prejudice or prevent a thorough investigation. If serious enough, it may be better for the health care service to forward any findings or evidence to the GMC or similar regulatory body.	Agreed this is the process that is proposed.
A qualified Yes, I would have a concern of the adequacy of the complaint process if information was not shared due to "exceptional reasons to justify it" if this was due to concerns over legal liability. It is important for both sides is to understated if something has gone wrong and if so how it could be prevented in the future.	Agreed

Within the responses received, there were 6 main elements related to the following themes:

1	Legal action and legal liability	(25%)
2	Dissatisfaction with current process	(25%)
3	Supportive of the proposals	(12.5%)
4	Independent from Government	(12.5%)
5	Supportive and open service	(12.5%)
6	Suggestions out of scope or not applicable	(12.5%)

Q.5.4 If you disagree that complaints should continue to be investigated properly and responded to if the complaint is also planning to take legal action, then please provide further comment.	
You Told Us:	**DHSC Response:**
All too often when a complainant is taking legal action the only reason for the investigation to continue is to avoid a court case and having to pay out compensation. It would be better if the service concerned were honest and admitted liability when they were in the wrong. Continuing to investigate a case is just a delaying tactic.	Noted, the majority of respondents were in support of complaints continuing to be investigated properly and responded to if the complaint is also planning to take legal action and so this exemption will be removed in the final version of the Regulations.
We have a duty of candour and responsibility to investigate and support the complainant and the accused	
Any exclusions in a complaints process is discriminatory.	
If you disagree is rather pointed and does not outline the actual position. I would like to make the following comment. I think the complaint should continue to be investigated. At the moment PST and the IRB reject the complaint if the complainant threatens legal action which may be after months or years of delay. However PST or the IRB do NOT have a policy of telling a complainant that the minute they put in writing they intend to take legal advice the shutters come up. The IOM does not have no win, no fee lawyers or citizens advice. Legal advice is expensive, for instance a petition of doleance will cost someone at least 20,000 (plus costs of a similar amount or more if the complainant loses). In most cases the complainant is at the end of their tether to threaten legal advice, having been pushed the current ineffective complaints system. To be absolutely clear, the threat of legal action should not halt the complaint progressing.	
Completely - open , transparency and fairness	

Complaints should most definitely be further investigated, however this is wholly dependent on the severity of the complaint and the actions taken by the complainant.	
The UK Ombudsman states: We need to look at whether you could get an answer to your complaint by taking legal action - like going to court or a tribunal about the problem. This is because the law says we cannot investigate a complaint if you have (or had) the option to do this. However, the law also says we can be flexible, and so we will look at what the right option should be to get an answer to your complaint. If we can see that there is (or was) a possible legal route to answer your complaint, we will talk to you to get a detailed understanding of your concerns and what you want to happen. We make sure we take into account factors such as how much it might cost you to take legal action, and how long it might take. If it looks to us like legal action would fully answer your concerns, or be able to give you all the results you are looking for, we may decide this is a better option for you.	This proposal is specifically in relation to the service provider (not the Ombudsman body). There is guidance from the Department of Health in England that service providers should continue to investigate to resolve the complaint quickly. In relation to the Ombudsman body, it is anticipated that they would follow the UK Ombudsman guidance and under standard consideration G of the Regulations would not take further action if legal action would be a better option for the complainant.

Within the responses received, there were 4 main elements related to the following themes:

1	Agree investigation should continue	(55.6%)
2	Neither agree nor disagree	(22.2%)
3	Disagree that investigation should continue	(11.1%)
4	Not applicable/relevant to question	(11.1%)

Q.6.2 If you disagree that 20 days should be the normal statutory response time for complaints, please provide further comment.	
You Told Us:	**DHSC Response:**
Should be sooner	The majority of respondents agreed that a 20 day standard timescale, with the ability to extend that in more complex cases where a longer investigation is required, is the best option and so this will be retained within the Regulations.
But it was not adhered to in my experience.	
In my experience this is not usually achieved currently, revised timescales are not offered and the complainant is not kept informed of progress	

I think in general an investigation could take longer I suppose it depends on the complexity of the case.	
Too long a period, especially if someone is stressed/ upset about the situation.	
20 days should be the maximum. 14 days should be sufficient for all but the most complex cases. Where there has been a death, the complaint and the response should be routinely copied to the Coroner of Inquests within the 14 day period.	
I agree that it should be 20 days but this box says comment only if you disagree. However I have the following comment, please define "regular". The update must also be meaningful. Define "promptly", i.e. give a timescale. Sometimes part of a complaint can be dealt with but holding the whole response back adds to complainant frustration. Providing woolly excuses for delays can also lead to further frustration for the complainant.	
It's fair	
As long as the complainant is informed of this at the outset, if there are problems in achieving this the complainant would be told	
20 days for an initial response yes but a thorough investigation cannot be conducted in 20 days	
All complaints should be treated individually and handlers allowed to decide how long to allocate to a complaint. Some can be resolved in a couple of days but more complex complaints need time to be properly investigated. Surely the quality of a response is more important than the speed at which it is received? If six months is acceptable in the UK why not here? Maintaining the 20 day limit places additional pressure on staff which, in turn, leads to mistakes and even more complaints!	

Within the responses received, there were 4 main elements related to the following themes:

1	Timescale is too short	(38.5%)
2	Timescale is too long	(23.1%)
3	Supportive of the proposals	(23.1%)
4	Not supportive that timescale is achievable/will be followed	(15.4%)

8.1. What are your views about the proposed membership of the combined IRB?	
You Told Us:	**DHSC Response:**
Appears reasonable and proportionate	The Department has considered the responses to part 1 and part 2 of the Complaints Modernisation consultations, along with the practicality of setting up a new Independent Review Body for an interim period, and decided that it would be of greater benefit to the public to move towards setting up an Ombudsman body at the earliest opportunity. Following consultation, the Department's preference would be for an independent Ombudsman with the remit to review unresolved health and social care complaints to be set up independently from the Department and Manx Care. However, it is not possible to set up such a body under Regulations; therefore, as an interim solution an Ombudsman body with the same membership that was outlined for the combined IRB will be established as this was supported by the majority of respondents. Members will be able to be appointed from both on and off-Island.
Should not include any politicians.	
Sounds good	
Local people are fine so long as the complainant has the right to say that they object to someone hearing their case. Please do not ship over any more members of anything from the UK. Also - meetings via computer are fine - but what kind of pay are they all going to be getting. Please do not make room for yet more staff at this level.	
It should be some people who are not medical based at the hospital	
Reasonable	
At least one member needs to have a legal background	
Need experience of processes within health and social care	
They must be absolutely independent and their interests/circumstances should be publicly declared in order to show this.	
Preference given to members who live on the island.	
Outside the island members is a great idea. Too many boys clubs mean independence is lost. It will gain perspective also.	
I'd prefer off island people as it is too "in house" and untrustworthy here	
Happy with proposed	
OK	
See previous comments. Diverse group of individuals who may not understand the complexities involved in difficult clinical decisions or legal ramifications.	
I feel that increasing the number of members from 6 to 9 members is just creating jobs for the boys. It doesn't benefit the complainant.	
Social Services doesn't seem enough Not sure it would be independent enough. Agree would be useful on a small island to include off island people to increase independence. Department no longer provides any health or social care services. It would have set out what services need to be provide by Manx Care etc. under a	

mandate so I would have thought there would have been a conflict of interest in terms of true independence. It may be an improvement in the short term but even the appearance of a conflict of interest can be damage the reputation of the IRB.	
Having members from outside the Isle of Man seems to be essential to ensure objectivity and counter any conflict of interest re local members.	
Sounds expensive. Although I appreciate the necessity for independent review. Will the members have knowledge of the challenges posed within an island health care system??	
Agree	
Yes. I can go along with that, but I think it would be sensible to review the system after 18 months in the first instance.	
Members should be independent of Manx Care but need to have some members who have a health qualification Could look to set up with some members coming from across	
Membership should be completely independent. Possibly done on a system like jury service. Steps should be taken to minimise cronyism, jobs for the boys and yes men.	
There should be a majority of people representing patients on the board if it is to be taken seriously by members of the public	
Sensible.	
Maybe include a lay person, for balance.	
I feel only one health and one social care qualified individual isn't enough. From a health point of view, it would be beneficial to have the 9 members proposed plus one additional, independent member of a healthcare profession, be able to join the panel (e.g. a physiotherapist who would work to a different skill set as, say a paediatrician)	The Ombudsman body will be able to take additional expert advice if necessary to consider a complaint properly.
In the event that insufficient candidates with "relevant experience" apply for membership of the combined IRB, what will be the next acceptable criteria? A review of the cases put forward for investigation by the combined IRB will be necessary in order to ascertain whether the 6:3 split between health and social care is appropriate, or whether any changes are required going forward.	The Ombudsman body will be able to take additional expert advice if necessary to consider a complaint properly. It is impossible to know the amount of cases that will be referred for review to this body as it is likely that the number of cases will expand from the current number but forward for review by the NHS IRB; therefore, flexibility has been built in to the Regulations to allow the membership to expand and contract as necessary.

This will be as bad as or even worse than the current IRB which was not fit for purpose. The new IRB needs to take a Tribunal format with a legally qualified chair. It needs to consist of one suitably qualified individual experienced in medical negligence cases, one senior retired medical expert (with no connection whatsoever with the Island) one former CQC inspector, one retired nursing sister (with no connection whatsoever with the Island) and three lay members. It should have the ability to seek written independent opinion from a panel of approved experts in all areas of medical expertise.	The Ombudsman body will be able to take additional expert advice if necessary to consider a complaint properly.
No concerns about the number of members. There needs to be enough to provide a range of relevant expertise, so 9 appears to be sufficient. I feel that it would be a positive step to open up membership to suitable persons who are not based on the Island. This would provide greater flexibility for the Appointments Commission to ensure that the right complement of expertise and qualifications can be appointed to the combined IRB. Perception of independence is almost as important as whether it is actually independent. There will be perception from the public that the combined IRB will not be sufficiently independent as it will be funded by the DHSC and the DHSC and Manx Care are still perceived to be one and the same in many respects. However, the long term plan to replace the combined IRB with a fully independent adjudicator hopefully within a few years is welcome and I accept that the combined IRB is an improvement over the current arrangement for independent review of complaints in health and social care in the Island.	
Depending on the nature of the complaint being investigated could be advisable to have a lay member or members with specific personal experience of the matter being investigated. For instance matters investigating issues regarding service users with moderate or severe learning difficulties should include experienced family carers who by that experience fully understand the issues involved. This could include one of the professional appointees if they have personal experience of the matter being considered	
It is important they are competent and experienced and accessible.	
The current IRB do not appear to be qualified or independent, the AG provides legal advice to them, and the Director of Public Health provides medical advice. Once established the IRB should be allowed to appoint their own not via the Appointments Commission set up by Government.	

I believe that any committee needs to have INDEPENDENT CLINICAL EXPERIENCE OR ACCESS TO CLINICAL EXPERIENCE IT SHOULD NOT BE HOUSED WITHIN CROOKALL HOUSE IT NEEDS TO BE ACCOUNTABLE FOR ITS ACTIONS to SOMEONE I have experience of the IRB and they are unguided and untrained in the role and therefore complaints have not in the past been fairly or thoroughly investigated On challenge, any challenge is not accepted in a positive way.	
I personally feel that 9 members may be too much for such a small community. There is also a concern that if the complainant should meet the board that they may feel overwhelmed by the amount of board members involved in the process.	It is impossible to know the amount of cases that will be referred for review to this body as it is likely that the number of cases will expand from the current number put forward for review by the NHS IRB; therefore, flexibility has been built in to the Regulations to allow the membership to expand and contract as necessary. Additionally, members are only paid for the time spent reviewing complaints.
It looks like you've tried to cover all bases. It's whether it works in practice and can evolve and change where required	Agreed, it is intended that the independence of the body will be increased in future under the Reform Bill.
Yes independent views from U.K. sources would be useful as the island can be termed as one big coronation street where most people know or can be related to the complainant	Conflicts of interest will be required to be handled and flexibility to allow an independent reviewer if all members are conflicted will be reflected within the Regulations.
Having persons with medical/nursing, social care and judicial/legal admin experience is essential. However appointment must be carefully considered so there is no perception of bias by recent connection. I do not favour off Island appointment. There has been little or no Tribunal training for members of Tribunals on which I have sat for approaching 30 years. Funding and arrangements are essential. Adequate remuneration is also essential. The current employed status of HS IRB by DHSC contradicts independence. These are senior quasi legal posts. They should be paid on Payment of Members Expenses rates. Nearest analogue is the IoM OFT Financial Ombudsman Service.	It is agreed that adequate remuneration is essential to attract the right calibre of people to be members of the Ombudsman body. It is intended that the payments to these members will be aligned with payments to the adjudicators of the Financial Service Ombudsman Scheme.

Within the responses received, there were 7 main elements related to the following themes:

1	Include legal and medical professionals	(26.7%)
2	Supportive of the proposals	(20%)

3	Independent from Government	(17.8%)
4	Include Off-Island members	(17.8%)
5	Local Members only	(8.9%)
6	Include lay members as well as professionals	(8.9%)
7	Number of members is too high	(6.7%)

8.2. What are your views about the proposed requirements in respect of experience, qualifications and training of members?	
You Told Us:	**DHSC Response:**
Appears reasonable and proportionate	Noted
They should be able to bring in specialists as required.	Agreed, the Ombudsman body will be able to seek advice from experts as necessary.
I think it's great	Noted
The proposed requirements all sound fine to me. However - please do not put members on this board who think they are superior to everyone else on the planet or who are trying to be "political" or a professional Civil Servant. Just plain speaking, honest members who understand what it is like to try and get justice.	Noted
Training and experience essential	Noted
Should be considered the same as a legal tribunal where a legal body is present - not necessarily the chair - but present to ensure all legal requirements are being adhered to.	Agreed, it is proposed that the Ombudsman body's chairperson will legally qualified.
See above. The review should be renamed adjudication and, ultimately, the members should be ombudsman adjudicators with a Senior and deputy senior selected by the members, not the AC	Following the consultation, the IRB will be renamed the Health and Social Care Ombudsman Body.
a recognised qualification' is vague Could specify graduate-post graduate-professional	Recognised qualification is defined within the Health and Social Care Ombudsman Body (Constitution. etc.) Regulations 2021.
Great, I think there should be 2 with recognised qualifications in healthcare though. People need to understand why things are done certain ways.	There must be at least 1 qualified health professional and 1 social worker but more could be taken on at the discretion of the Appointments Commission.
do it properly and not the usual, "that'll do" cock up	Comment noted
More emphasis on patient as customer Acknowledgement that we as users contribute Power and feelings of entitlement on both sides n disputes needs experienced communicators to resolve	Noted
It looks like your trying to put all the relevant professionals in place	Thank you for your comment.
A non-question. Surely the members will be concerned members of the public, fully aware of what they are involved in. I question what form 'training' will take.	Noted

The role of the IRB has been to investigate an appeal once the clinical, ethical and legal arguments have already been examined. They are not qualified to give an external expert report.	The role of the Ombudsman body will be to review unresolved health and social care complaints and make recommendations to resolve the complaint. It will be the final stage for health and social care complaints.
My only concern about the proposed requirements is that if a complainant were to go to mediation that the members sitting on the panel could in retrospect confuse the complainant with legal jargon. A complainant would find that situation very daunting.	Complainants can be supported at any meetings.
Yes	Noted
Perhaps more members with qualifications in health and social care	Currently there is a requirement for at least 2 members with health and social care qualifications in Regulations, but the Appointments Commission could take on more if it felt that that balance was required within the membership of the Ombudsman body. Additionally, there will be the ability for the Ombudsman body to request expert advice, if required.
As long as this is not at vast expense to the taxpayer. There are already people dealing with complaints employed by the hospital. Use them.	This is for an independent review if the person is not happy with the review done by the healthcare provider. Membership is based on current membership of IRB so no increase in people dealing with complaints but remuneration is being considered.
As above view on membership, but also agree that relevant experience, qualifications and regular training of members	Noted
From personal experience I cannot over emphasise the importance of ensuring any candidates for IRB membership are given as much detail as is possible about the type and complexity of the cases they may be faced with if successful, and also the amount of time a thorough investigation will take - researching background, interviewing, preparing reports etc. It has been known for a successful candidate to resign after one meeting due to the lack of information provided at the interview stage. The level of financial compensation bears no relation to the amount of time, work and effort required to complete a thorough investigation. I believe structured complaint handling training should be compulsory and completed before a member is entrusted with a case.	Thank you for your comments, the Department will support the Appointments Commission to provide such information to candidates. The payments to members of the Ombudsman body are being considered and it is likely that they will be aligned to payments made to adjudicators under the Financial Services Ombudsman Scheme.
1. Chair: Non practising Advocate or Solicitor 2. Expert in medical negligence: Non practising Advocate or Solicitor 3. CQC member retired by no more than five years (on appointment) 4. Nursing sister retired by no more than five years (on appointment) 5. Three lay members with experience of "life"	Thank you for your comments. It is intended that an Ombudsman body with the same membership that was outlined for the combined IRB will be established as this was supported by the majority of respondents.
Agree that there must be ongoing training requirements and that there should be a minimum number of hours for each Member per annum.	Noted. The actual requirements will be set by the Ombudsman body.

it is imperative if the mistakes of the past are to be avoided that every individual selected must be able to show that they have the necessary training or experience to manage the role they are assuming	Noted
Training should be provided and should be on an ongoing basis.	Noted
The IRB should have Ombudsman or medical qualifications and be regulated for maladministration by the Tynwald Ombudsman, this can be changed to a truly independent adjudicator in due course when the IRB are replaced. I note above you mention experience in "administrative justice ". The current IRB do not deal with administrative justice, are you attempting to bypass the Tynwald Ombudsman to review the work of the IRB for maladministration / public injustice, i.e. the IRB will be marking their own homework ? The legally qualified (therefore regulated) Tynwald Ombudsman should be reviewing the IRB now, as voted for by Tynwald 15 years ago and this should be implemented in November 2021. The IRB have not stated publicly if they are actually qualified to look at administrative justice.	The proposed interim Ombudsman body will be made up of a range of qualified and experienced members with the chairperson being legally qualified. As this is the last stage of the complaints review, it is not considered necessary to submit the Ombudsman body to the jurisdiction of the Tynwald Commissioner for Administration as this would add a further step to the process, undermine the Ombudsman body's decisions and potentially complicate matters. It is intended that the future Independent Ombudsman will be set up completely independently from the health and social care system and will have the remit to look at complaints in relation to maladministration / public injustice of Manx Care.
Training Is essential Clinical input is essential and also someone that understands , process , procedures, consent and is able to resolve issues	Noted
Agree training is vital	Noted
I can't say because I don't know enough about the people involved.	None
As said above important that some members have medical qualifications. A good training package is essential	Noted
Membership should be open to all sections of the Manx community, regardless of educational achievement. Motivation, commitment, independence, communication skills and decision making skills should be the criteria. Also honesty.	Thank you for your feedback; however, the majority of respondents agreed with the proposed membership (which only included professionally qualified or experienced members) and so this is what is reflected within the updated draft Regulations.
Very little experience is necessary on the board for the identification of adverse incidents or genuine mistakes as reported by patients	
There needs to be representatives from different professional groups within health services to allow for a more rounded view.	Agreed, although only 1 health and 1 social worker are required within the Regulations it will be for the Appointments Commission to determine the correct balance for the membership of the Ombudsman body from those that apply for the role. The Ombudsman body will be able to request expert advice, if necessary.

I believe that there should be at least two members of the board who are qualified in Health and one in Social Care to provide the board with insight. The manager of the complaints department should also be on the board to provide insight on the nature of complaints, as well as provide consistency and continuity on behalf of the service and for the benefit of the complainant.	The Department does not agree that the manager of the complaints department should be a member of the Ombudsman body as this would affect its independence. However, the Ombudsman body will be able to require information from the service provider in order to gain knowledge about the nature of the complaint and how it has been handled by the service provider.
Experience and training seems reasonable. Need to ensure Department does adequately fund the training.	Noted
Requirements in respect of experience, qualifications and training of members is essential, to ensure that a professional, objective and fair system is provided.	Noted
Would perhaps be more appropriate to have healthcare-heavy IRB for healthcare reviews and social care heavy for social care reviews. Again, I would be concerned that the IRB members would not be aware of the specific challenges posed by island healthcare	It is anticipated that the Ombudsman body would convene a group of members with suitable experience to review the complaint.

Within the responses received, there were 6 main elements related to the following themes:

1 Members to have professional qualifications in health, social care or law (27.9%)
2 Supportive of the proposals (25.6%)
3 Members to be trained in procedures/background of Manx systems (18.6%)
4 Not relevant to question (9.3%)
5 Qualifications not a priority, lay members instead (4.7%)
6 Other responses: (14%)
- External specialists available to IRB members
- IRB to be similar to tribunal or Ombudsman

8.4 Do you think that any ongoing training requirements should be set out within the Regulations - please provide reasons for your response.	
You Told Us:	**DHSC Response:**
I'm not convinced that this level of detail needs to be in regulation and should be more within policy	Your comments have been noted. It is proposed that a requirement to undertake regular training is set out in Regulations but any detail in relation to the training requirements is set out in guidance by the Department rather than within the Regulations.
They need to be able to deal with complaints to decide about them so will need this training often	
On-going training in any field is essential if only to remind people of their responsibilities. Complacency can soon set in. And then yet another little "silo" of members is created.	

Things change and training will ensure up to date responses	
Someone that was appointed 10 years ago will be lacking in knowledge and updates unless they take it upon themselves to train. Health and Social Care environments are rapidly changing, training should be provided to ensure these changes are kept up with.	
In service training is essential	
Improve understanding and importance of independence	
Ongoing training is vital to ensure procedures are followed and to pick out any poor practice	
If it's set in law that ongoing training is provided then surely it can only get better	
Self-evident.	
I agree with the training aspect but with reservations.	
So that complainants can be confident that experience is appropriate.	
It is vital that, as health care (and, no doubt the Manx Care organisation) develops, members should be brought up to date with current practice and research	
this would protect the staff	
When I was a member of the IRB I frequently mentioned training and asked what would be provided. However nothing was organised. The only positive step was the introduction of historical case reviews at meetings where the complaint handler could explain the issues, outcome etc. It was also apparent that the various members of the IRB came from very different backgrounds and some without any complaint handling experience. Ongoing training would have helped us to provide a consistent approach to investigations.	
Primarily to adhere to timescales and to keep up to date with any new precedents.	
currently there appears to be no process in place that requires individuals to validate the claims they make in regard to their suitability for any role they assume beyond basic qualifications which give no indication as to whether that individual has kept pace with changes within their particular discipline or become negligent in the way that they fulfil their professional obligations to the service	
Yes they need to be accountable to the patient and practitioner	
So that all members are aware of what is required	
Very few people would have the experience from their usual employment.	

Training needs will vary on panel makeup. More suitable may be a budget for training.	
To ensure that the board do not settle in to procedural bad habits and to evolve with the needs of patients	
Needs won't be fully evident until the team is up and running.	
Ongoing training should always be provided to ensure the service is up to date with all processes.	
To ensure the training is ongoing and well-funded to that people are kept up date.	
Unless a trusted body that specifies these training requirements has been appointed by regulations or statutes.	
For transparency and confidence in the process	
There should be learning outcomes from complaints. These could be shared as a training tool	Agreed.
Yes all ongoing training should be published in the regulations along with IRB annual reports every year, annual accounts, progress etc. A set amount of relevant CPD should be required (provided by third parties) It is disappointing that at the time of writing (11th October 2021) the IRB have not issued their annual report for year ended 31st March 2021 or made any public comment regarding these proposals. As stated earlier, the modus operandi of the IRB has been stagnant since 2004 and the vote by Tynwald in April 2021 made it quite clear that change to health complaints procedures are needed urgently. As an MHK said, complainants have been pushed to the brink by the current process. The IRB have stayed silent throughout, not one public comment that I can locate. Put very simply, the IRB needs a huge wake up call. The IRB make no attempt to reconcile with complaints on their service, they tell you they will refer to the Attorney General. Annual reports demonstrate good governance, the last IRB report was for a 4 year period 2016-20. Governance and public relations should be high on the list. An annual public meeting held by the IRB should also form part of the regulations.	Your comments have been considered as part of the changes proposed to the IRB following consultation. The proposed Ombudsman body members will be required to publish details of the training undertaken within its annual report.
I am sure I here is a template in North West Hospitals to be followed	Noted
They must not be used in the manner proposed even as an interim measure. It would be unfair to the complainant and them.	This response is not applicable to the question.
It's more about honesty, integrity, and being unfettered than training.	Noted

Anything called mandatory seen her as pointless and pen pushing. Romanian towards concept claim call need always put before strain ng. In my experience acceptable to not turn up or five apologies waste spaces not acknowledge or value the time costs and tick a list of it affects pay performance or appraisal	None

Within the responses received, there were 3 main elements related to the following themes:

1 Supportive of the proposals, with emphasis on: (65.9%)
- Training to be undertaken regularly
- Ensure independence and impartiality
- Help maintain high professional standards
- Learning outcomes used for training purposes
- Provide reassurance/support for staff and service users
- Ensure timescales are adhered to

2 Alternative suggestions, including: (9.8%)
- Undertaking accredited qualifications
- Publication of all training requirements and training undertaken

3 Not supportive of the proposals (4.9%)

9.1. Do you have any comments on the remit and time limit for making a complaint to the combined IRB?	
You Told Us:	**DHSC Response:**
No enforcement powers, no changes then	Thank you for your comment. It is proposed that Manx Care will be required to prepare an action plan stating how it (or its contracted providers) will implement the actions recommended by the Ombudsman body. The Department will then ensure that Manx Care completes the actions set out within the action plan. This is a change from the current process.
No	None
I think this time limit is fair although on the Isle of Man with so many temporary staff it is not always easy to get an answer or find the person if they have left the Island	Thank you for your response.
no, seems reasonable	Thank you for your response.
No	Noted
No	None
No	None
The proposed changes. Allowing the complaints at a later stage. And even at the discretion of the chairperson	Thank you for your response.

The longer time proposed is much needed. In the case of a death, time is needed for the relative of the deceased to deal with grief and feel strong enough to deal with the complaints progress. I speak from personal experience.	Thank you for your response.
Given that I am currently involved in a complaint that has not achieved resolution after more than three years your twelve month timescale is pointless The only way the IRB can look at complaints fairly is to have open access to external expert review.	The IRB will be replaced by an Ombudsman body that will have the ability to access expert advice, if necessary.
No comment	None
No Spot on as above for the reasons stated	Thank you for your response.
No	None
Agree with it	Thank you for your response.
No, they seem reasonable.	Thank you for your response.
The time frame should be extended indefinitely for any case where new evidence comes to light that was not available in the first 12 months.	Flexibility is given to the Ombudsman body to decide to extend time limit on a case by case basis.
The change in time limit for requesting a review is extended in most cases, but is potentially a zero time limit for some complaints made to service providers after 6 months and less than 12 months from the date they become aware of the issue. All it takes is for the service provider to take longer than 6 months to provide a final response to a complaint that has been made 6 months after becoming aware of the issue and then there is no time remaining for requesting a review. Perhaps the time limit for making a complaint in the first place is too long or the time limit for requesting a review needs extending further? One way or another there seems to be a conflict with the two stages having the exact same time limit even though one stage is meant to follow after the first stage has been completed.	Thank you for your comments. The Regulations will be amended to allow a complaint to be made under stage 2 within 12 months of becoming aware of the problem or within 3 months of the date of decision of formal response at stage 1, whichever is longer.
I believe the one year time limit is a significant improvement on the previous time limit however I think it important that the Chairpersons ability to extend this time limit in cases where clear evidence of a breach of process by the department is documented should be enshrined as an automatic process allowing investigation of that apparent breach of process to be fully investigated	The Regulations will allow the proposed Ombudsman body to review complaints outside of the timescale on a case by case basis.
No. An extended timescale makes sense.	Thank you for your response.

No other than the Tynwald Ombudsman should have jurisdiction for review rather than just the individual personality of the IRB Chairperson.	Your comments have been considered but on balance it has been decided that under the Regulations, the Ombudsman body will be the final point of escalation for health or social care complaints. This will keep the complaints process as a simple 2 step process that is for people to understand and access. Where complainant dissatisfaction about matters of process is concerned (i.e. they way in which the Ombudsman body has handled their substantive complaint about a health or care provider), the Ombudsman body will be required to constitute its own 'corporate' complaints process for considering such matters.
I believe this is fair	Thank you for your response.
No	None
No	None
No seems fair to be same as UK	Thank you for your response.
Time limits should be in line with professional bodies too e.g. HPC, NMC, GMC, Dentists etc. Speedier responses should be encouraged and credit given. Time limits can be counterproductive.	Your comment has been reviewed and considered; however, the professional bodies all have their own processes for review concerns and complaints and some, such as the GMC, do not have a time frame. Therefore, no changes have been proposed to the timeframe for making a complaint.
An exception should be made when the capacity to make a complaint has been delayed for medical reasons. This is especially relevant long term severe debilitating may have been caused by Manx Care	There will be the ability for the time limit to be waived in circumstances such as this.
No.	None
Agree there should be considerable flexibility on the date a complaint can be made because of the issues mentioned in the copy above. Concern that is it the discretion of 1 person and what would the process be if they didn't consider it. Also people may have been put off making a complaint if they had tentatively tried to raise one.	It would be at the discretion of the chairperson of the Ombudsman body to review a complaint that was made outside of the stated timescales and that decision would need to be made on the individual circumstances and information available to him/her at the time.
Allowing sufficient time for a service user to request a review is essential to take into account the fact that the person may not be in a fit state to deal with progressing things	Thank you for your response.

Within the responses received, there were 4 main elements related to the following themes:

1	Time limit should be flexible / case by case basis	(25.7%)
2	Supportive of the proposals	(17.1%)
3	Not supportive of the proposals	(5.7%)
4	Not relevant to question	(2.9%)

10.1 Do you have any comments on the proposed process or standard considerations for the initial review?	
You Told Us:	**DHSC Response:**

I hope it goes forward	Thank you for your response
Just so long as what you have said above is adhered to especially the meeting with the complainant - made simple for the complainant and they are actually listened to. Please do not make all this investigation process the usual tick-box exercise I have found it to be over here (or in the UK!). Also - please do not make it into some kind of "fight" between the IRB and the complainant. Lessons can be learnt from everyone - and learning opportunities occur everywhere. This must always be at the forefront of any review/investigation.	It is agreed that the main focus of complaints handling should be on what learning can be taken. This aim has been key to developing these proposals.
No	None
I find the reference to MHRT confusing. Application to MHRT is for limited purpose, namely whether or not statutory deprivation of Liberty and compulsory treatment should be continued or the patient discharged. MHRT does not deal with complaints about service delivery. A patient may wish to be discharged and have a complaint about service delivery. They are two separate things. There is no reason to delay one whilst the other is considered. They can run in parallel.	It is agreed that the MHRT does not consider complaints about a service delivery. This comment was made in the relation to complaints that may be made about being detained under the act or treatment provided whilst detained. The aim of the consideration is to clarify that complaints about statutory deprivation of liberty and compulsory treatment, where the result that the complainant wishes to achieve is discontinuation of treatment or discharge, should not be made to the Ombudsman body.
Can a relative or carer make a complaint on behalf of another person who may not be able deal with form filling and high level meetings?	Yes this is already included within Regulations
Timeframes and communication are really important	Agreed
Other ways alongside webpage bus shelters benefits offices local meeting places health and social care settings in prescription bags	It is agreed that a variety of publication and distribution methods should be used to communication with the public about this service.
There seem to be some fantastic proposals there and can they start with me	Thank you for your response
None	None
The IRB can only judge whether any resolution proposed is fair and reasonable if it has a complete understanding of all details of the case, which inevitably means an external expert review.	The Ombudsman body will have the notes of the complaint review from the service provider to review and make that judgement. They will be able to call for further expert advice if necessary to form a full understanding of the case.
No Comment	None
No	None
No	None
Agree with the proposals	Thank you for your response
No, I think it is a practical proposal and positive step forward.	Thank you for your response
The initial review should also address directions as to the further progress of the investigation of the complaint	It is agreed that the complainant should be given some indication of what will happen to their complaint after the initial review. This is covered in the Regulations.

Should it be possible to extend the deadline of 20 working days for notifying the complainant of the decision whether to investigate the complaint if it has not been possible to arrange a meeting with the complainant within 15 working days? For example, if the meeting were to happen on day 19 or day 20 then it would be impractical for the combined IRB to make its decision and to notify the complainant of its decision by day 20, but under the proposal as outlined above there would be no option to extend the deadline as the meeting was held within 20 working days. Content with the other proposals except the time limit for requesting a review by the combined IRB appearing to conflict with the time limit for making a complaint as I have detailed in my prior comments.	Thank you for your comments. It is agreed that flexibility is required in this circumstance and this has been allowed for in the Regulations.
the proposals seem sufficiently far reaching to deal with most if not all matters brought before them and hopefully when fully enacted will prevent the numerous historic failures of the service to properly consider or investigate serious complaints in regard to systemic failures	Thank you for your response
No.	None
Standard form - if a letter has all the info required the IRB don't need to back to the complainant, (possibly bereaved) with a box ticking exercise to now complete a form. Some discretion should be applied, or at the very least the IRB complete the form and meet the complainant to sign off etc. A formal IRB Register - All enquiries and complaints shall be recorded in the IRB register and numbered consecutively Initial meeting - The Secretary must offer the Complainant the opportunity to meet the Clerk if the Complainant wishes to discuss he nature of the complaint, the remit of the IRB and presentation of the case the Convenor (Recommendation 2b of 33/06). Time limit - Why is it the Chairperson to make the decision and not convenor 1 and 2? Convenor file reviews - records must be kept in writing in accordance with good Governance Consideration - 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. (What like GMC? GMC has 12 month timescale, complainants might be timed out!) 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	Thank you for your comments and suggestions. The Regulations have been reviewed to ensure that a complaint can be accepted in any format, if it contains the necessary information. A meeting is required to be offered to the complainant so this could be used as an opportunity to gather any further information. The Regulations will not got to the level of detail to specify how records must be maintained by the Ombudsman Body. This will be for the Ombudsman Body to set out for itself. The operation of the NHS IRB and SS IRB have been reviewed as part of putting together these proposals, along with Ombudsmen in other jurisdictions and the best practice position that appears to suit the Island has been selected. As part of this a change has been suggested to ensure that the chairperson of the Ombudsman Body will be required to be legally qualified. The aim of the considerations is to ensure that the complaint is reviewed by the correct body and to reduce duplication. The Ombudsman Body should not review a complaint that falls outside its remit. It also ensures that the Ombudsman Body is required to look at all complaints that do fall within its remit.

consideration in this paragraph. (How can the IRB make this judgement, they are not legally qualified) Convenors 1 and 2. Currently the IRB have a system of review by a 2nd convenor. This should be part of the regulations. 33/06 was quite clear that a 2nd convenor was still required (this was agreed by Tynwald 15 years ago - 33/06 -Motion 2d). The regulations should state that process includes convenor 1 and 2. The complainant was also given the right to request a meeting with the convenor following their decision (33/06 2c). The IRB are currently lay people and therefore a four eyes principle is required. Governor - the role of the Governor should be defined by regulation Complainant questions - If the complainant has questions regarding the requirement, the IRB must answer same (they ignored my questions repeatedly and the regulations should state that reasonable questions should be answered) Legal privilege - Can the AG just say the records are subject to legal privilege ? Who decides this? Evidence that legal privilege applies must be provided to the IRB and reported to the Complainant. What about legal disclosure rules? IRB review - must be in accordance with generally accepted good practice. File notes of telephone conversations, records kept, genuine independence. In my case I was expected to review medical records and provide comment and not once did the IRB ask DHSC (the professionals) to do same. I provided a detailed list on failures in local resolution (some with evidence) and the IRB failed to take this up with DHSC. Not once did they contact DHSC, all the work was put on the bereaved complainant. The IRB has to demonstration lack of bias. Oral hearings - The Complainant should have the right to attend any hearing and provide feedback to the IRB prior to a decision being made. If an oral hearing is for a staff member only and not a complainant, there has to be a right to reply otherwise it may be seen as a kangaroo court. IRB complaints procedure - I have not been able to locate this, was it included in the consultation? If not it should have been as it is relevant to the consultation. IRB case reports - if they are not produced within the given timescale of 6 months the IRB must lay a report before Tynwald, advise why the report has not been finished and provide a deadline for producing same. Tynwald Ombudsman - should be included in the IRB procedure for reasons as mentioned previously Government advisors - i.e. the Attorney General	

Office and Director of Public Health should NOT be allowed to give advice to the IRB. IRB advisors should be independent of Government. The AG providing legal advice and the Director of Public Health providing medical advice is not viewed as independent by the public. Annual report - In addition to the requirements per regulation: Internal complaints about the IRB should can be from a number of sources, to the IRB, the Tynwald Ombudsman, and an MHK. A register of complaints should be maintained and open for inspection by the Ombudsman. ALL complaints, from whatever source, should be included in the annual report and what the IRB did to resolve them. There should be a requirement for them to issue a written apology if it turns out they got it wrong. There should also be a requirement for the IRB to meet a complainant. Also in the report, transparency on advisors, i.e. details of any third parties used to provide additional advice, medical, legal, accountancy, training etc. The IRB annual report should also include the IRB annual accounts and proposed budget for the following year, Governance statement, and proposals for the following year. The IRB annual report should be direct to Tynwald by 30th June each and every year which ensures that pressure could not applied to the IRB by DHSC or Government about the report contents prior to publication.	
I believe that the statement 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). Could be interpreted in many ways For example in Clinical negligence, a court may hear this but again the person may not have the funds for litigation. There has to be an option for all	Thank you for your comments. The statement within the Regulations is further defined - the aim of the considerations is to ensure that the complaint is reviewed by the correct body and to reduce duplication. The Ombudsman body should not review a complaint that falls outside its remit. It also ensures that the Ombudsman body is required to look at all complaints that do fall within its remit.
Not at this stage	None
This seems fair. However, bearing in mind that there will be older people involved as well, information should be available to them in paper form somehow.	Agreed
No	None
Why can't the paperwork be reviewed there and then as is done at the passport office?	In the interim position, the members of the Ombudsman body will not be full time members of staff; therefore, this suggestion cannot be accommodated. However, it will be considered when the fully Independent Ombudsman is established as a statutory board.
The board should only exclude itself from the complaint process in the case where the patient or the patient's representative has made a complaint to the GMC or other professional body and to only meet after that body has published its findings.	Thank you for your comments. The aim of the considerations is to ensure that the complaint is reviewed by the correct body and to reduce duplication. The Ombudsman body should not review a complaint that falls outside its remit. It also ensures that the Ombudsman body is required to look at all complaints that do fall within its remit.

The process should be easy for the complainant, so if they not filled in the correct form helps should be given to do so, that shouldn't be a reason not to consider it. Also concerned over many of the considerations as especially the complaint may want an independent body to look at, so that should override some of the consideration or it not really offering an independent place to complain. 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)	Thank you for your comments. A complaint would not be able to reject because it has not been made on the correct form. If someone is struggling to put their complaint in writing they will have an opportunity to meet with a member of the Ombudsman body to discuss it and could be signposted to an Independent Advocacy service for further support. The aim of the considerations is to ensure that the complaint is reviewed by the correct body and to reduce duplication. It also ensures that the Ombudsman body is required to look at all complaints that do fall within its remit.
No. I do feel this consultation is quite lengthy and as a result many people will be put off completing it There will no doubt be a bias in the returned responses, with those with lower educational attainment under represented.	Thank you for your response

Within the responses received, there were 3 main elements related to the following themes:

1 Supportive of the proposals (19.4%)
2 Should include alternative and accessible communication approaches (19.4%)
3 Other responses, including: (22.2%)
- Timescales
- External reviews
- Internal review processes
- IRB record keeping

11.1. Do you have any views on the proposed process set out for the combined IRB's review of a complaint?	
You Told Us:	**DHSC Response:**
Appears reasonable and proportionate	Thank you for your comment.
The service provider when getting a complaint isn't just going to say yes this is true. It needs looking in properly the service users reply does not matter. What matters is if it happened or not and that needs thoroughly investigating	Matters will be investigated thoroughly at the local resolution stage. The Ombudsman body will be able to get access to the service provider's records to assess whether the complaint has been handled fairly.
You must ensure that all relevant documentation is made available to the IRB's in a timely manner	Thank you for your comment which the Department agrees with.

The complaint should be investigated, adjudicated and determined by a single IRB member. It should be issued as provisional with either the Complainant/service user or service provider being able to make submissions about issues with which they disagree. The IRB adjudicator should then review and issue a final. This could then be subject of review by a second adjudicator. Presumption should be on paper determination unless complex or difficult evidential questions arise	Thank you for your comments. It will be for the Ombudsman body to determine how it will review a complaint within the process set out within the Regulations. The Ombudsman body will be required to set out the process used within a code of practice that is available to the public. It is anticipated that this will follow the best practice guidelines issued by the Scottish Public Services Ombudsman.
Good that people can be accompanied.	Thank you for your comment.
No	None
It seems all clear and transparent	Thank you for your comment.
Oral evidence from the complainant should be the norm.	Oral evidence can be taken from any complainant that wishes to give it.
This is the first mention of independent expert advice. Who will provide this? How does the IRB decide to seek this? Is it going to be readily accessible? In my view it should be offered to the complainant in all serious cases at the investigation/meeting stage when resolution is not agreed. This is too important to be left at the whim of the IRB, and possibly subject to undisclosed restrictions.	It will be for the Ombudsman body to set out how it will seek its independent expert advice.
If the service provider cannot supply the information within 6 weeks and is then given another time scale then that leaves the process open to abuse by the service provider. They should be able to supply the information within 6 weeks as I consider that as ample time.	The timescales for provision of the information by a service provider have been brought into line with the requirements to provide data in relation to a data subject access request under data protection legislation.
An appeal timescale should be incorporated	However, if a complainant is unhappy following the outcome then this could be raised with the Ombudsman body directly through its corporate complaints process, or legal redress could be sought.
Full feedback to all parties including if no case to answer is found	Agreed
Can any of the details be shared publicly albeit anonymously	Yes, it is already set out within the Regulations that reports are published in anonymised form
Agree with timescales and processes	None
The proposed process appears reasonable, however, from experience, sometimes the information required for an investigation is not available in an easily accessible format. Complex cases can involve documentation produced in many different areas over a period of time and these will often times be provided in chronological order rather than by type. Sometimes too, during an investigation, it becomes obvious that certain documents are missing and these have to be found before further work can be done. Bearing this in mind, it is possible that the timeframe for completion may have to be extended but this is something that will vary from case to case.	The Department wishes to give further flexibility for the Ombudsman body to complete its reviews of complex cases and it is intended that this will be reflected in the Regulations.

28 days is ample time to provide requested information. There should be a financial penalty for unreasonable delay and compensation to the complainant.	The timescales for provision of the information by a service provider have been brought into line with the requirements to provide data in relation to a data subject access request under data protection legislation.
I am content with the proposals detailed above.	Thank you for your comment.
Seems balanced	Thank you for your comment
No.	None
Yes please see earlier comments in Q10, pasted below for ease of reference. Standard form - if a letter has all the info required the IRB don't need to back to the complainant, (possibly bereaved) with a box ticking exercise to now complete a form. Some discretion should be applied, or at the very least the IRB complete the form and meet the complainant to sign off etc. A formal IRB Register - All enquiries and complaints shall be recorded in the IRB register and numbered consecutively Initial meeting - The Secretary must offer the Complainant the opportunity to meet the Clerk if the Complainant wishes to discuss he nature of the complaint, the remit of the IRB and presentation of the case the Convenor (Recommendation 2b of 33/06). Time limit - Why is it the Chairperson to make the decision and not convenor 1 and 2? Convenor file reviews - records must be kept in writing in accordance with good Governance Consideration - 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. (What like GMC? GMC has 12 month timescale, complainants might be timed out!) 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. (How can the IRB make this judgement, they are not legally qualified) Convenors 1 and 2. Currently the IRB have a system of review by a 2nd convenor. This should be part of the regulations. 33/06 was quite clear that a 2nd convenor was still required (This was agreed by Tynwald 15 years ago - 33/06 -Motion 2d). The regulations should state that process includes convenor 1 and 2. The complainant was also given the right to request a meeting with the convenor following their decision (33/06 2c). The IRB are currently lay people and therefore a four eyes principle is required.	Thank you for your detailed comments, which have been responded to above.

Governor - the role of the Governor should be defined by regulation Complainant questions - If the complainant has questions regarding the requirement, the IRB must answer same (they ignored my questions repeatedly and the regulations should state that reasonable questions should be answered) Legal privilege - Can the AG just say the records are subject to legal privilege ? Who decides this? Evidence that legal privilege applies must be provided to the IRB and reported to the Complainant. What about legal disclosure rules? IRB review - must be in accordance with generally accepted good practice. File notes of telephone conversations, records kept, genuine independence. In my case I was expected to review medical records and provide comment and not once did the IRB ask DHSC (the professionals) to do same. I provided a detailed list on failures in local resolution (some with evidence) and the IRB failed to take this up with DHSC. Not once did they contact DHSC, all the work was put on the bereaved complainant. The IRB has to demonstration lack of bias. Oral hearings - The Complainant should have the right to attend any hearing and provide feedback to the IRB prior to a decision being made. If an oral hearing is for a staff member only and not a complainant, there has to be a right to reply otherwise it may be seen as a kangaroo court. IRB complaints procedure - I have not been able to locate this, was it included in the consultation? If not it should have been as it is relevant to the consultation. IRB case reports - if they are not produced within the given timescale of 6 months the IRB must lay a report before Tynwald, advise why the report has not been finished and provide a deadline for producing same. Tynwald Ombudsman - should be included in the IRB procedure for reasons as mentioned previously Government advisors - i.e. the Attorney General Office and Director of Public Health should NOT be allowed to give advice to the IRB. IRB advisors should be independent of Government. The AG providing legal advice and the Director of Public Health providing medical advice is not viewed as independent by the public. Annual report - In addition to the requirements per regulation: Internal complaints about the IRB should can be from a number of sources, to the IRB, the Tynwald Ombudsman, and an MHK. A register of complaints should be maintained and open for inspection by the Ombudsman. ALL complaints, from whatever source, should be	

included in the annual report and what the IRB did to resolve them. There should be a requirement for them to issue a written apology if it turns out they got it wrong. There should also be a requirement for the IRB to meet a complainant. Also in the report, transparency on advisors, i.e. details of any third parties used to provide additional advice, medical, legal, accountancy, training etc. The IRB annual report should also include the IRB annual accounts and proposed budget for the following year, Governance statement, and proposals for the following year. The IRB annual report should be direct to Tynwald by 30th June each and every year which ensures that pressure could not applied to the IRB by DHSC or Government about the report contents prior to publication.	
Timescale fine Representation _ is this legal?	Thank you for your comment on the timescale. It is not clear what is meant by the comment on representation. People giving evidence or advice to the Ombudsman body can be accompanied by another person that could be a friend, a carer, a legal representative or an independent advocate. We have looked into whether legal aid is available for supporting people in making representations to the Ombudsman body and unfortunately it is not. This will be something that will be considered further under the Reform Bill.
No	None
If there are delays for any reason, the complainant should be informed. No need for any great long letters, just letting them know.	Thank you for your comment, which the Department agrees with.
All people giving evidence should be allowed to have someone present	The Department agrees with this statement and it is specifically allowed for in the Regulations.
The process is too focused on the process being correct and not on the people/persons involved. The human factor should be core, not the administrative function.	It is agreed that the process must engage with the people involved in a positive way to ensure that they feel heard and respected. However, this is not something that can be legislated for. The legislation must set out the process to be followed in a clear way. The implementation of the arrangements required by the legislation will be key to ensure that this is the case.
It is very rare for one health care provider to give evidence against another in line with most medical defence unions so this proposal seems to lack safeguards to the detriment of patients generally	The proposals do not suggest that one health care provider to give evidence against another. The Ombudsman body can request service providers and complainants to give more information verbally, if necessary, to aid their understanding of the issues when reviewing the complaints documentation.
No.	None
Seems reasonable	Thank you for your comment.
No	None

Within the responses received, there were 4 main elements related to the following themes:

1	Supportive of the proposals	(22.9%)
2	Timescale is too long	(14.3%)

3 Giving of evidence and representation (8.6%)

4 Other responses, including: (31.4%)

- Impartiality
- Review by single IRB member
- Appeals
- Feedback
- Publishing

12.1. Do you have any comments about the combined IRB having the final decision on a complaint referred to it?	
You Told Us:	**DHSC Response:**
Appears reasonable and proportionate	Thank you for your comment.
If they are trained in handling it then let's hope they take it seriously and look into it. Hopefully they will have no personal bias towards any providers	Noted
It should not have the final decision. There should be a method to appeal their decision on a complaint. My main concern is that these investigations do get decisions wrong and the same mistakes in a department happen again and again. That means no lessons learnt. I am not saying that the IRB should be coping with a prospective vexatious complainant - this should of course be weeded out. However, there are times when erroneous decisions are made by these types of investigative bodies - you only need to look at the UK for examples.	Thank you for your comment which has been considered; however, review mechanisms need to stop somewhere and so it has been decided that the Ombudsman body's decision should be final and no further stage of review will be made available to complainants after the independent review by the Ombudsman body (other than to seek legal redress). If a complainant is unhappy with how the review of the complaint has been carried out then the Ombudsman body will have a complaints process that the person can follow to ensure that his or her complaint has been fairly considered by the Ombudsman body.
Why do we have to do as the UK, why can't the government here make it for the Island? Many professional medical staff have left due to the way things work in the background. Any complaint decision should be able to be queried if there is a good enough reason.	
It's unjust that a complainant cannot take the matter further.	
If the complainant is really unhappy (and it is not just a case of someone ploughing on with a complaint because they haven't been told what they want to hear) then there should be a further stage available.	

Who will ensure that the IRB's recommendations are put into practice?	To ensure that recommendations are acted upon, mechanisms for more transparency and accountability for implementing the recommendations of the Ombudsman body have been included within the Regulations, such as the Ombudsman body being required to report to Tynwald annually on any recommendations that have not been implemented. Additionally, it will become standard practice for anonymised versions of the Ombudsman body's reports to be made available publicly, Manx Care will be required to state publicly if they are unable or unwilling to implement the recommendation and to give a reason for not implementing it, and the Department will be required to hold Manx Care to account in implementing the recommendations.
No	None
No	None
No	None
There has to be an end of the line somewhere. As long as it's clear, transparent and as fair as possible	Thank you for your comment.
Provided there is no proven bias between a panel member and the complainant (small island)	Thank you for your comment. Members of the Ombudsman body will be required to declare conflicts of interest and not act in such cases.
Agree with the proposal	Thank you for your comments.
If ongoing training is to be provided then this should mitigate the need for an internal complaints procedure for what is a very small group, i.e. the process being followed should be fully understood by all the IRB members and training given regularly to ensure new members are brought up to speed as soon as possible.	It is agreed that the process to be followed should be set out clearly for Ombudsman body members and the public to understand. Ongoing training will be provided to Ombudsman body members.
Yes. Having waited for three years for an entirely incompetent IRB outcome there should be a right of appeal to a Deemster and a cost effective judicial review process other than a petition of doleance. Non means tested Legal Aid should be made available in all cases where there are sufficient merits in the legal argument. I would not rule out the use of the office of Coroner where there has been a death. The public have to be protected from the poor service I received from the IRB.	It is accepted that there is public dissatisfaction with the current IRB process. However, the changes proposed within the draft Regulations should ensure that the Ombudsman body is made up of experienced professionals that follow a transparent process to reach a conclusion on complaints reviewed. Therefore, it is considered that the Ombudsman body should have the final decision on complaints referred - any further review could undermine the Ombudsman body's powers. However, if a complainant is unhappy following the outcome then this could be raised with the Ombudsman body directly through its corporate complaints process, or legal redress could be sought.
I agree that the combined IRB should have the final say about a complaint referred to it by a complainant and no further right of appeal beyond this point.	Thank you for your comment.
seems eminently fair though I would like specific mention to be made that where a potential criminal breach of legislation has taken place by any party the combined IRB should have the power to refer the matter to the criminal justice system	Specific mention is not necessary for a matter to be referred to the criminal justice system
No.	No comment

"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." The comment above does not reflect the actual situation at the PHSO who state "Our decisions are final and there is no automatic right to have a review, but we will consider whether to review our decision if we have got something wrong." Further detail regarding PHSO feedback can be found at https://www.ombudsman.org.uk/about-us/feedback-about-our-service Also what happens about public injustice and maladministration which the IRB say they don't deal with. Who does the public complain to in relation to Manx Care and DHSC? Feedback forms should be issued to the public and reported on.	Thank you for your comments which have been considered. The Ombudsman body will be required to set out a corporate complaints process which will allow people to complain to them if they feel that the Ombudsman body has not followed due process or to ask for further consideration to be given to a matter and review the decision if it has got something wrong. Complaints about maladministration can still be made to the Tynwald Commissioner for Administration. The Department intends to put in place a memorandum of understanding between all of the parties that could be involved in looking at complaints to ensure that where there is a potential overlap of powers that those involved in reviewing complaints work together to ensure that the complaint is review by the most appropriate body and ensure that this is made clear to the complainant.
I believe that a process has to be followed and any errors or omissions the IRB should be accountable for or the person providing the information I believe that any INFORMATION placed before the IRB should be disclosed and agreed by BOTH PARTIES	A process will be required to be outlined by the Ombudsman body as a code of practice. Any complaints about the Ombudsman body not following this process will be required to be disclosed in its annual report to Tynwald.
Not at all.	No comment
No	No comment
No	No comment
None but if the IRB does not uphold a similar percentage of complaints as experience in the UK, confidence in it will quickly run out. Any decision by the IRB won't prevent a referral to the GMC or other body.	Thank you for your comments. It is agreed that any decision by the Ombudsman body will not preclude the complaint being taken to an individual's professional body or a complainant from seeking legal redress.
Okay IRB to have final decision on complaint as long as it doesn't preclude any legal redress being available as well. Would need to look how IRB were monitored to ensure robust processes were under taken.	Thank you for your comment. The proposals would not preclude legal redress from being available following a review by the Ombudsman body. Monitoring of the Ombudsman body will be via annual reporting to Tynwald on the work undertaken and any complaints made about its handling of complaints.
Seems appropriate	Noted

Within the responses received, there were 5 main elements related to the following themes:

1 Supportive of the proposals (26.5%)
2 Not supportive – unfair for IRB to have final decision (11.8%)
3 Supportive with emphasis on accountability and fairness (11.8%)
4 Supportive but concerns regarding enforcement of recommendations (5.9%)
5 Other comments, including (14.7%)
- Availability of Legal Aid
- How many complaints will be upheld
- Options for situations outside remit of IRB

12.3 If you think that there should be a mechanism for a further review of how the combined IRB has handled a complaint, who do you think should fulfil that role and what value do you believe that review would add?	
You Told Us:	**DHSC Response:**
An advocate or QC	Thank you for your comments.
I think complaints should be looked into thoroughly if they have been looked into there is no harm in another organisation checking the review to make sure it adds up and the decision is agreed upon	The Department agrees that complaints should be looked into thoroughly and that it is important that there is another organisation to check and review the decisions taken; however, further reviews and reviews of reviews cannot continue forever. There must be a point where the decision is final. Therefore, it has been determined that the 2 stage process set out which consists of local resolution of a complaint followed by independent review is sufficient to ensure that complaints are investigated thoroughly.
Need some sort of ombudsman service.	It is agreed that an Ombudsman would be a good option for the Island and so changes have been made to the proposals so that an Ombudsman body will be set up as an independent reviewer of health and social care complaints.
There is always value in reviewing complaints and about Health and Social Care and how they have been handled. Too much has been swept under the carpet over the years or simply been ignored. People have also been made to feel ostracised if they dare to complain. I do not know enough to advise on the best person to actually perform this role - perhaps a retired Deemster.	The Department agrees that complaints should be looked into thoroughly and that it is important that there is another organisation to check and review the decisions taken; however, further reviews and reviews of reviews cannot continue forever. There must be a point where the decision is final. Therefore, it has been determined that the 2 stage process set out which consists of local resolution of a complaint followed by independent review is sufficient to ensure that complaints are investigated thoroughly.
Someone completely impartial that can provide a review on a papers basis.	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints.
It's satellite litigation. If IRB gets it wrong judicial review is available.	The Department agrees and so proposes that the decision of an Ombudsman body cannot be appealed other than by recourse to a legal challenge.
Purely on the administrative aspects of the complaint-how it has been handled.	In relation to the administrative aspects of how a complaint has been handled, the Ombudsman body will be required to have a complaint procedure in respect of the way in which a complaint has been considered, i.e. the process not the decision on the original complaint
A Deemster, independent review	Thank you for your comments
I feel the review should be handled by someone who has nothing to do with government or the IRB. This would give the complainant the satisfaction of knowing that the review was handled fairly.	It is proposed that the decision of an Ombudsman body can only be reviewed by recourse to a legal challenge.
To stop decisions being made on the basis of professional friendship/colleagues backing each other up	The Ombudsman body members will be a group of professionals with a chairperson that is legally qualified. This group will be able to carry out an unbiased review.
Independent ombudsman	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints. It is proposed that the decision of the

Yes absolutely there should be such a mechanism. The role could be fulfilled by an advocate (legal)	Ombudsman body can only be reviewed by recourse to a legal challenge.
Department and the hope that gaps in process would be rectified for future complaints	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints. It is proposed that the decision of the Ombudsman body can only be reviewed by recourse to a legal challenge. The Department will have a role in assuring that the recommendations of the Ombudsman body are implemented.
Health Minister This should fall under the Health Minister's remit to ensure statutory obligations have been upheld.	A Minister's role is to head a Department of Government, making and implementing decisions on policy and strategy of the national health and social care service. Therefore, it is not considered appropriate that the Minister reviews decisions about complaints in relation to the provision of individual services.
As above. The Tynwald Commissioner for Administration is currently failing to meet timescales and taking more than two years for a simple complaint. The Department have already proved incompetent to handle this sort of matter. The right of appeal must go to a Deemster or we must look to appoint a second Coroner of Inquests with a dual role to deal with these matters	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints. It is proposed that the decision of the Ombudsman body can only be reviewed by recourse to a legal challenge.
Making the IRB subject to review by the Department would certainly be anathema to the public. Doing a similar thing with the Tynwald Commissioner for Administration would only add another layer and drag out process for longer without any added value. Otherwise, if perceived that an external review would be valuable in case the adjudicator got something wrong, we could then add a further layer again to request a review by another body into how well the Tynwald Commission for Administration has handled her review also? The same principle could be applied ad infinitum. It is very important that the independent adjudicator's decision is final. Best practice in the UK for an ombudsman is that there should be an internal complaints procedure for service users to make a complaint to the ombudsman about how the ombudsman has potentially mishandled a review into a complaint about health or social care services - this is already included in the proposals detailed here, with the combined IRB required to have an internal complaints procedure.	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints. It is proposed that the decision of the Ombudsman body can only be reviewed by recourse to a legal challenge. As stated here, the decision of the Ombudsman body will be final in respect of the substantive complaint (i.e. a subjective discretionary judgement on a set of agreed facts). However, the ombudsmen in the various UK jurisdictions operate corporate procedures by which a complainant can make a quite separate and distinct complaint about the way in which their complaint has been considered, i.e. the process not the decision on their original complaint. This was proposed and remains the intention.

I am unsure who may be best placed to fulfil this role. A review can give added oversight and ensure that due process has been followed.	
Yes Tynwald Commissioner for Administration should be appointed now as she is a legally qualified person and has previously raised concerns about the IRB. The IRB should not be allowed to mark their own homework effectively. For a small organisation a number of complaints have already been made to the Tynwald Commissioner for Administration about the IRB. Some complainants have suffered the death of a loved one and feel they have been failed by the complaints system. By appointing the Tynwald Commissioner for Administration she can review the existing files for maladministration and layout any training requirements. I do not believe the IRB should deal with maladministration of Manx Care/DHSC, it should be direct to the Tynwald Commissioner for Administration. It is a legal matter and the IRB are not qualified to make comment. However in general, I would like the IRB and Tynwald Commissioner for Administration (for health complaints) moved off Island. The Tynwald Commissioner for Administration decided not to investigate DHSC or the IRB to be "pragmatic". I believe she should have completed her investigation into DHSC and the IRB bearing in mind the seriousness of what could go wrong if maladministration was found (harm or worse, death). In the interim though, appointing the Tynwald Commissioner for Administration is better than nothing at all.	
There needs to accountability and therefore I believe that the actions of the IRB should be audited and challenged if appropriate	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints. It is proposed that the decision of the Ombudsman body can only be reviewed by recourse to a legal challenge.
Probably cabinet office. All people involved in complaint need somewhere to refer too if they believe complaint has not been handled correctly	
Rather than a review an audit	
Could be okay without this level as long as IRB was monitored and process were robust. If yes suggest Tynwald Commissioner for Administration.	An Ombudsman body will be set up to carry out independent reviews of health and social care complaints. It is proposed that the decision of the Ombudsman body can only be reviewed by recourse to a legal challenge.
Only in exceptional circumstances.	

Within the responses received, there were 8 main elements related to the following themes:

1	Legal professional, e.g. Deemster	(17.9%)
2	Independent body, preferably off-Island	(17.9%)
3	DHSC/Health Minister	(14.3%)
4	Tynwald Commissioner for Administration	(7.1%)
5	Independent Ombudsman	(7.1%)

6 Not sure (7.1%)
7 Role not required (3.6%)
8 Other responses regarding what value the review would have: (25%)
- To step in if IRB makes mistake
- To ensure transparency, accountability and impartiality
- Only used in exceptional circumstances
- Only to review handling of the complaint

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?	
You Told Us:	**DHSC Response:**
It should be fully transparent. If Government needs more funding it should make cuts in other areas such as the Cabinet Office.	Noted. The Department intends to be fully transparent in its reporting.
No	None
Please ensure that all reports are written in easy to understand use of the English Language. Not in the usual quasi-legal, political civil-service format that we usually get. Nice user friendly clear and simple English please. Also ensure that any graphs are user friendly not the confusing efforts we normally get.	Agreed
No	None
Number of complaints, key concerns raised, what has been done to rectify some of the complaints.	Agreed. It is proposed that the report will cover the following items broken down by area of care: - the numbers of complaints received - the subject matter of those complaints - a summary of how they were handled including the outcome of the investigations into those complaints; - a statement outlining changes or improvements to services or procedures as a result of consideration of complaints.
No	None
Complaints about lack of adequate services in a particular area of the island or for a particular group of people?	It is proposed that the report will cover the subject matter of the complaints.
How much time was wasted chasing complaints down rabbit holes in a desperate attempt to try and find something to hang on the staff member?	It is proposed that the reports will include a number of factual items such as: - the numbers of complaints received - the subject matter of those complaints - a summary of how they were handled including the outcome of the investigations into those complaints; - a statement outlining changes or improvements to services or procedures as a result of consideration of complaints.
No	None
Any changes recommended and made	Agreed - this is proposed to be included in the annual reporting.

Yes. Numbers of complaints against medical practices should be published annually. Numbers of complaints against individual services provided by the hospital likewise Numbers of complaints against services provided by e.g. social services/ home care etc.	It is proposed that the reporting will be broken down by area of care.
Inspection, monitoring, scrutiny of the complaints process should be carried out rigorously and reported publicly on a regular basis. Reports written by those subject to scrutiny have little value.	Under the Manx Care Act 2021, the Department is required publish its assessment of Manx Care's performance on an annual basis. The letter required will set out any areas of improvement identified as part of the Department's assurance process.
I would like to see information on which service providers refused to follow Discretionary Recommendations.	Each service provider will be required to report on complaints where recommendations of the Health and Social Services Independent Review Body were not acted upon, giving the reasons why not. This will be done on an annual basis. The Ombudsman body's report is also proposed to cover information in relation to outstanding recommendations, including how long they have been outstanding.
Open, honest, and transparent information. Complaints per health care area	Thank you for your comment. The Department intends to be fully transparent in its reporting. The annual reporting is proposed to be broken down by area of care.
I would want to see complaints reported	Agreed - a summary of the complaints received is proposed to be included in the reporting.
Level of work of all departments, number of compliments, number of complaints, number of complaints resolved, number of complaints ongoing, number of complaints referred to IRB, learning gained from events (especially those of a similar nature), plans for future improvement	Thank you for your comments. It is planned that all of these areas will be covered in the requirements for annual reporting, except the number of compliments. It is agreed that it would be helpful to see the number of compliments received for balance; however, this cannot be contained in the Regulations as it is not directly related to the topic of complaints. There will not be any barrier to service providers from publishing the number of compliments received as well as the number of complaints.
Clear, easily understandable information presented in a format that can be accessed by everyone.	Thank you for your comment; this will be the aim.
Cost of investigations, percentage of resolved cases, any Action taken against Professionals etc.	Thank you for your comment; however, the Department does not consider it appropriate to publicly report this information.

I agree that fines and offences will not help but sanctions will. There does have to be the ability for the IRB to bring finality to a situation in either recommendations or a published narrative. It is pointless just saying what has gone wrong without actually doing something about it. The findings of the IRB have to be completely binding on the Department and Manx Care.	It is very uncommon for an Ombudsman body to issue binding recommendations. The proposal is that the Department will oversee Manx Care's implementation of the recommendations. The Ombudsman body's public report will contain a report on all outstanding recommendations made by it in respect of any reviews completed in the report period, which will be subject to Tynwald scrutiny. Under the Reform Bill, consideration will be given to the Ombudsman having the power to recommend compensation of one form or another, including consolatory awards for 'out of pocket' expenses, and more significant awards in recognition of distress, frustration and delay, and for substantive losses incurred as a consequence maladministration causing injustice. Further research into this is required before a policy decision can be taken.
Agree with the proposals above.	Thank you for your comment
no	None
No.	None
Timescales for laying report (not as soon as reasonably practical). Whilst writing this, DHSC has not filed the annual complaints report to 31.03.21, it is now overdue. The IRB have not published their annual report. Annual reports should be by 30th June each and every year. The current regulations state lay an annual report before Tynwald but because the current regulations don't say lay an annual report EVERY year, then this hasn't happened. Good governance dictates timely reports. The public don't get the option to file annual reports as soon as possible, we are given timescales, as are other Government Departments. Failure to file on time should be notified to Tynwald and published on the DHSC website. Nowhere in the consultation have you mentioned that the PHSO issue financial payment to complainants in accordance with England. I would rather the IRB report laid directly before Tynwald and not via DHSC/Manx Care. This will ensure report contents are not up for discussion or amendment prior to publication. Please see earlier comments about Governance, independent advisors etc. The headline is: Transparency, accountability and assurance. However I can't see any accountability in the regulations and there are areas of this consultation that have not been very transparent.	Changes have been made to the Regulations to bring in fixed timescales for laying the reports before Tynwald.
Complaint i.e. Consent Action and evidence I would want to see INSIGHT and Evidence from the Service Provider or DEPT	It is proposed that the reports will include a number of factual items such as: - the numbers of complaints received - the subject matter of those complaints - a summary of how they were handled including the outcome of the investigations into those complaints; - a statement outlining changes or improvements to services or procedures as a result of consideration of complaints.
This information should be available to the public	Agreed - it is proposed that the reports will be made public.

I can't think of anything extra.	Thank you for your consideration.
Type of complaints. Whether all dealt with in correct timeframe. Learning outcomes have been implemented.	Thank you for your comment. All of these areas are proposed to be covered in the reporting.
The report should contain statistics on adverse event across the services to demonstrate year on year service improvement and openness and how many of these led to complaints.	Reports on unintended or unexpected incidents that have caused harm are already required to be reported under the duty of candour procedure.
No.	None
Number of complaints broken down by department and area, with outcomes, process used, patient satisfaction, and learning outcomes.	Thank you for your comment. Post consultation, it is proposed that the annual reporting will be broken down by area of care and will: (a) specify the numbers of complaints received in relation to the services provided under the mandate by the relevant service provider; (b) identify the subject matter of those complaints; (c) summarise how they were handled including the outcome of the investigations into those complaints; (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; (f) identify any complaints where recommendations of the Health and Social Services Ombudsman body were not acted upon, giving the reasons why not; and (g) include a summary of the training that has been provided during the year in relation to complaints.
Seems reasonable although any Data Protection issues may need to be considered if the details could identify someone	Agreed - care will be taken to ensure that the information given is summarised and will not identify individuals. This is a requirement of data protection legislation in any case.
I would have concerns that patients could be identified if anything specific is reported - it's a small island. Surely this kind of information should be handled with sensitivity and only anonymised or heavily redacted info be available only as a FOI request	

Within the responses received, there were 8 main elements related to the following themes:

1	Wide range of statistics	(34.1%)
2	Evidence of implementation / Accountability	(24.4%)
3	Transparency	(9.8%)
4	Time spent on complaints / Adherence to timeframes	(7.3%)
5	Sensitivity and discretion	(7.3%)
6	Accessibility	(4.9%)
7	Supportive of the proposals	(4.9%)
8	Not supportive of the proposals	(2.4%)

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?	
You Told Us:	**DHSC Response:**
I would, I think it's important to promote a culture where complaints are welcomed as an opportunity to improve services and try to move away from a "blame game". I don't think any service can ever be perfect oh and mistakes will happen and because the service providers are human beings. To my mind important thing is that the services try to be customer/patient/client focused: to be truly caring	Post consultation it has been decided that annual reports from all service providers will be required to be provided to Manx Care to be included within Manx Care's annual reporting. Manx Care's annual report will be made public. Some service providers are small organisations and so to require them to publish their annual reports individually could inadvertently require them to identify sensitive personal information about a service user. The Department will publish an template report for completion by smaller providers to assist them in meeting this additional reporting requirement.
Yes. People should be responsible for their actions, good or bad. However - please do not create an extra department for this.	
Definitely! These should also be publicly available to provide the transparency and openness promised by this piece of work	
Yes, that would demonstrate the effectiveness of the complaints handling process to its full extent.	
Not by regulation. Perhaps encouraged as good practice or perhaps required by contract. I would view it as beneficial to the public confidence in individual service providers and also beneficial to good governance of the service providers for them to publish such information. However, some smaller service providers may struggle to comply with requirements if they are over regulated.	
This may depend on the size of the organisation. Larger providers, yes. Smaller providers may need more flexibility in terms of capacity for these reports.	
Yes, each GP, Dentist, Optician etc. should be under an obligation to publish their annual complaints report and provide same to the public if requested.	
Yes, most certainly otherwise what is the point of it.	
I think an overall report via Manx Care would suffice, broken down by department	
Yes, you'd imagine that the resulting scrutiny would encourage the service providers to reflect and ensure that learning / outcomes were achieved.	
see above (from a public perspective) Outcomes and learning to be shared within the organisations to employees only	
Yes	Thank you for your response

Yes it would be helpful to know they are being looked into and taken seriously	It is proposed that annual reports from all service providers will be required to be provided to Manx Care to be included within Manx Care's annual reporting. The reports will contain detail on complaints received including changes or improvements to services or procedures as a result of the complaints. Manx Care's annual report will be made public. Some service providers are small organisations and so to require them to publish their annual reports individually could inadvertently require them to identify sensitive personal information about a service user.
Absolutely. Current reporting (out with COVID) in terms of journey times, appointment times, waiting list timings are not transparent and should be so.	Thank you for your comment which has been noted. However, this consultation is specifically in relation to reporting on complaints.
Yes	Thank you for your response
Yes	Thank you for your response
What courses have been provided and how many attended would be useful.	Thank you for your comment. This has been considered and it is proposed that a summary of the training that has been provided during the year in relation to complaints or learning from complaints will be reported upon.
Yes	Thank you for your response
Yes	Thank you for your response
No	Thank you for your response
Yes	Thank you for your response
Yes but not the dreaded lessons have been learned blanket statement	Thank you for your comment. The reports will be required to contain a statement outlining what changes or improvements have been made to services or procedures as a result of the consideration of complaints.
No	Thank you for your response
As above	Thank you for your response
Yes	Thank you for your response
Definitely.	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response
fantastic	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response
YES	Thank you for your response
Yes.	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response
Yes	Thank you for your response

Within the responses received, there were 5 main elements related to the following themes:

1	Members to have professional qualifications in health, social care or law	(27.9%)
2	Supportive of the proposals	(25.6%)
3	Members to be trained in procedures/background of Manx systems	(18.6%)
4	Not relevant to question	(9.3%)
5	Qualifications not a priority, lay members instead	(4.7%)

15.1. Are there any other areas where this policy has the potential to adversely affect equality of opportunity?	
You Told Us:	**DHSC Response:**
No	None
Yes - especially the "them and us" syndrome. For example, the ordinary man on the street versus a government department - leading to high-handedness, treating people as inferior beings, making people feel they are in the wrong, un-necessary talking down to people. Please remember we are all equal - maybe different - but with equal rights.	This legislation will be implemented in line with equality legislation and policies.
No	None
This is to be welcomed	None
People who do not have capacity to make a complaint themselves? Children People with learning difficulties	People that lack capacity or struggle to make complaints can be supported by an independent advocate. Unfortunately the additional services for independent advocacy identified as a need within this consultation are not able to be brought in as part of these Regulations due to the limitations of the primary legislation. The regulations do however allow complaints to be made on behalf of people who lack capacity.
No	None
No	None
Access to buildings	It is agreed that meetings must be held in buildings that allow access for the complainant. This is required under the Equality Act 2008 and so does not need additional regulation.
Not that I can see	None
Mental health needs to be considered and acknowledged in terms of whether mental ill health is contributing to making false complaints/accusations	Agreed, this would need to be considered as part of considering a complaint. A change has been made to the Regulations to state that the response letter to the complainant must offer to supply the complainant with details of any services or support which it considers may provide assistance to the complainant, taking into account that person's needs.
No - if the amount of complaints and outcomes isn't transparent, people will lose faith in the system - especially on a small island.	None
Not that I can see at present	None
I am not aware of any other areas.	None
If run as a Tribunal all areas of equality will be met.	None

Nothing to add	None
think this area is being well covered	None
A public office where people can turn up to and talk to someone about complaints would be great. Many vulnerable people struggle with reading and making phone calls but are better communicating in person.	Thank you for your comment. The Department is required under the Regulations to provide face-to-face advice to people wanting to complain, to explain the correct process to follow. Additionally, service providers are required to offer meetings to complainants both at the beginning and at the end of the complaints review process and both service providers and the Ombudsman body will be required to accept oral complaints, if the circumstances warrant it. Consideration will be given to extending the MCALs service to be able to offer face to face advice following the trial period.
Dealing with the bereaved, mental health issues. For instance when an MHK has warned the IRB about a prolonged period of high stress for the complainant, the IRB should not describe the bereaved as "Previously I think that I am right to say that she would not provide a list as it was too distressing for her to do so. Her procrastination, even stubborn resistance to due process should affect her in some way? She is now using a kind of blackmail to sully our reputation" A request by the IRB that the bereaved should review complex medical records of their dead mother for a third time is unacceptable. The records included colour scans of the deceased mother's organs. Mental health issues are not an attempt to blackmail. When the IRB refuse to meet a complainant, insist their correspondence is in writing, words used by the IRB in response to the complainant include unproductive, pointless, semantic and strange. In other words, you are wasting IRB time, you are pointless, going on and on and rather odd. If the current IRB do not take the time to understand why the complaint is important to the complainant then they should pack up shop now. Meeting a complainants and developing trust is vital. Denigration of the bereaved and mental health issues (triggered by DHSC complaints process) is not acceptable on any level. DHSC telling a complainant that a consultant agrees his cancer care advice was not appropriate, is not an apology or reassurance that it won't happen again, just an acknowledgement that it wrong, it says "so what?" to a complainant. Training on language used by Complaints Manager and the IRB is urgently required. Lack of IT skill or literacy should be taken into account. Please see my notes on the regulations which are more detailed. The current IRB requirement for everything in writing precludes some people from making a complaint, assistance should be given at IRB level. IOMHCA only go up to local resolution level despite previous IRB leaflets indication IOMHCA could help. Communication for equality needs to be more general and not "put it in writing". A phone number for the IRB would be helpful. A website with meet the team. The public know absolutely nothing about the IRB, how can we complain to a faceless entity who won't meet us? Annual public meetings would be useful. PHSO provide a raft of information on their website. The	Thank you for sharing your experience. It is intended that the changes proposed will improve people's experiences of dealing with the Ombudsman body in future, for example, the members of the Ombudsman body will be required to be experienced and trained in dealing with complaints. Additionally, the Regulations will require the Ombudsman body to offer a meeting with the complainant so they will not be able to refuse such a request in future.

independent advocacy arrangement needs to be set up now and they should be medically/legally qualified. IOM Government has rooms full of qualified people, the complainant is currently on their own, in some circumstances pushed to the brink has recently mentioned in Tynwald.	
I would suggest Language The elderly may need help in understanding complaints and procedures	Thank you for your comment. Under the proposals, MCALS and the Department would be able to offer help and advice on understanding how and when to complain and the roles of the different organisations in the process.
Not that I can see at this stage,	None
No.	None
I am not sure	None
Yes. How will the policy help the illiterate, the disabled and the mentally infirm?	It is proposed that complaints can be made orally or a representative can make a complaint on behalf of someone else.
I have a strong belief that as long as we continue to tick boxes stating our ethnicity, sexuality etc. equality will never be achieved. Broken down by gender, adult/child should suffice	None
Ensure that someone with Mental Health issues or their representative of their choosing has access to the information they need to make a complaint and supported to do so if required and they are not precluded from doing so.	Thank you for your comment. The proposals should ensure that everyone understands how to make a complaint. The Regulations also allow anyone to nominate a representative to make a complaint on their behalf.

Within the responses received, there were 4 main elements related to the following themes:

1 Accessibility (20%)
2 Need for sensitivity (13.3%)
3 Supportive of the proposals (6.7%)
4 Other suggestions, including: (13.3%)
- Transparency
- Data Protection
- Diversity issues

16.1. Do you have any other feedback or information that you wish to share with us as part of this consultation?	
You Told Us:	**DHSC Response:**
You need to remove politicians who fetter outcomes.	Manx Care has implemented a "Supporting the work of elected members" policy that describes how politicians and Manx Care should interact to ensure that politicians and staff in Manx Care understand how politicians may raise issues with Manx Care in the appropriate way.
No, hope this will benefit the island	Thank you for your feedback.

When plans are drawn up for the scheme, in whatever form it takes, those involved should read Black Box Thinking by Matthew Syed. This has great information and comparisons to the airline and healthcare sectors and could be invaluable in considerations.	Thank you for your feedback.
Please do not let this legislation turn into simply a tick box exercise. There is far too much of that already within the Health and Social Care system. Please remember inclusivity is a real thing, not just imagination.	Thank you for your feedback.
I think IRB should have power to ensure that their recommendations are followed	The Department (in its regulatory capacity) will ensure that the Ombudsman body's recommendations will be followed.
The main thing in my view that needs to be dealt with is training in dealing with the people making the complaints. It's often not done lightly and ensuring there are repercussions for not dealing with it within the time frame given with no contact.	Agreed, training requirements are important and are covered in the Regulations.
At local resolution level, especially if experts reports are to be obtained, it is important that complainant and service provider agree. 1. The documents to be submitted 2. The questions to be asked The service provider should offer two experts in the alternative for the complainant to choose. In case of non-agreement the dispute could be referred to IRB for resolution and confirmation	The Department is moving away from getting expert reports and will instead be using the Ombudsman body to review any unresolved complaints. Service providers are required to offer complainants a meeting to discuss and clarify the complaint at an early stage in the process.
Good progress towards greater accountability.	Thank you for your feedback.
I think this will be a much better process	Thank you for your feedback.
One of the major cultural problems I see as a user provider is entitlement. There's no do as you would be done by/family friends as staff cut corners, bypass systems, and pull in favours to get the care they need and want. The worst practitioners therefore never experience secondary levels of care so have no real understanding of the average person's experience. Nothing is on the line or at stake if you have resources to go elsewhere or use system to your advantage. Squash poor badly paid nurses and overworked doctors myth in media. Highlight and reward other support systems. Stop allowing gifts sweets cakes junk food and then publicising same. Thank and publicise the people clerical support functions, behind scenes who make tiny steps towards the ethos and service you wish to promote.	It is agreed that there are cultural issues raised by this consultation paper that will need consideration as part of implementing the proposed statutory arrangements. Part of this will be to highlight and reward those that move towards the right ethos. Manx Care has mechanisms in place to share where good feedback has been received, which is a step towards this. Additionally there is a workforce and culture project in place as part of the Heath and Care Transformation Programme to deliver on Sir Jonathan Michael's 25th recommendation. Progress is being made focussed on the values of Manx Care as an organisation, on creating psychological safety in the workplace, creating a learning culture, recognition activities and wellbeing opportunities for Manx Care employees.

It is regrettable that DHSC has seen fit to employ a lawyer to advise on complaints. I gather he gives advice on individual complaints. Is this with the complainant's knowledge or consent? Why, if there is to be fairness and transparency, when a complaint is upheld and compensation is agreed, the DHSC demands that it is only paid on condition that a non-disclosure agreement is signed?	Thank you for your comment. Each case is considered on an individual basis.
I wish you every success in your endeavour to improve Social Care Services, but I have my doubts whether this service can change for the better. If you do manage to achieve your aims I will be the first to apologize.	Thank you for your feedback.
I am glad to see that a more robust complaints procedure is being implemented. It is long overdue	Thank you for your feedback.
No mention of Support for staff and what the process will be if no charge to answer is found	A change will be made to ensure that staff that are complained about receive a debrief following the investigation and are offered any necessary support.
Staff working in service areas need to be supported if complaints/allegations are being made against them , processes need to be fair Complaints need to be dealt with appropriately however fair consideration needs to be given to both sides; the Complainant and the service provider - patients/service users may not always be right	A change will be made to ensure that staff that are complained about receive a debrief following the investigation and are offered any necessary support.
The demands made of the IRB should not be under estimated. From experience some (actually, many) of the cases handled by the IRB should never have been got to this stage. Local resolution could be obtained in many instances if staff had followed good complaint handling practices. Allowing issues to develop further creates even greater animosity towards those involved at the outset and unwillingness of health professionals to meet with those affected does not help matters. There have been cases involving locum staff who have left the Island who then refuse to enter into discussions about complaints or provide any helpful information which might assist with resolution.	Agreed, it is the aim that the majority of complaints should be resolved by local resolution. Complaints made to the Ombudsman body that have not followed good complaint handling practices at local resolution level will be redirected to the service provider for a proper investigation and response with timescales imposed on achieving a resolution.
This consultation is too long, and some people might not understand all the language.	Thank you for your feedback, which we will bear in mind for future consultations.
I petitioned Tynwald in 2019 on this subject. Tynwald debated the subject in my absence and avoided the appointment of a select committee as a result. This was manifestly unfair and an abuse of process. The current proposals represent little or no significant improvement.	Thank you for your feedback. However, the Department disagrees that current proposals represent little or no significant improvement. Many improvements have been proposed to be implemented as a result of this consultation.
No	None
No.	None

Yes. Please see my detailed notes on the regulations. Overall I am very disappointed that despite 6 months there has been failure to bring in some of the basic public protection voted for and approved by 15 years ago. There has been no explanation of why primary legislation needs to be amended to bring in the Ombudsman/Independent Adjudicator. The Candour consultation recognised that timescales were required for reporting and promised the public had been heard and timescales would be added to the regulations. The timescales were not added and the Minister told Tynwald in April 2021 "Certainly, my personal view is if anything went over that three-month period, unless there was an exceptionally good reason that would not be without undue delay". It is appreciated Candour hasn't been going long enough, but based on the comments to Tynwald, the latest complaints reports should have been laid before Tynwald by 30th June or thereabouts. DHSC/Transformation Team should not use the term "as soon as" etc. because it does not promote good Governance. Deadlines should be inserted into the regulations. The latest reports could have assisted the public in making comments. This consultation has not mentioned that the PHSO recognise the harm and distress complaints can cause and make recommendations for financial remedies. This consultation does not mention this at all and I would have expected to see financial remedy in line with modern practice. As a general rule, the PHSO does not order large amounts but it does recognise accountability. There does not appear to be any accountability in these new regulations for failing to follow them. This needs to be addressed. There has been no detail as to what type of statutory body the IRB will be? There are many to pick from and following a freedom of information request last year, DHSC failed to provide any information. The legal status of a public body should not be a secret. So please can you tell the public, what type of public body are you setting up? I have made detailed comment on the actual regulations. There is no ability to upload documents to this consultation so I will email same under separate cover.	We have reviewed and considered all detailed notes and made a number of changes based on your feedback. New primary legislation needs to be drafted to establish a truly Independent Ombudsman, which is the intention. The full extent of the proposals could not be accommodated within current primary legislation or Regulations; however, the Department has tried to make as many changes as possible within the confines of the current law. Timescales have been tightened up where appropriate in the Regulations. Financial remedies will be considered under the Reform Bill. Accountability will be through reporting to Tynwald and the Department holding Manx Care to account in following through with any improvements identified as a result of complaints' investigations.
Thank you for asking me to participate I hadn't heard of the consultation so I don't think your message really got out Ill publish it today on Social Media as people do need to have a say but the document is long confusing and "jo public" will disengage in the survey	Thank you for your feedback. This was a complicated subject to consult on and attempts were made to simplify it and to push it via social media. However, we will continue to try to improve the messaging so that it is more easily understood in future.
Time will tell if you have got it right.	Thank you for your feedback.

No, this has been well thought through. My one fear is that a large Department will be formed taking funds away from the hospital budget. But, I don't know how many complaints you receive in a normal year.	Thank you for your feedback. It is not the intention to create any new 'departments' to manage this process. Complaints already need to be dealt with by service provider so these teams are in place. The Ombudsman body will be new but it will replace the 2 current independent review bodies.
Feedback of complaints should be readily available to staff whom complaints were about. On numerous occasions there have been no feedback to staff.	Thank you for your feedback. A change has been made to the proposals to require a full debrief for the staff member(s) concerned and support will be provided if necessary.
Will there be anything in legislation about the management of vexatious complaints? They are damaging to staff morale and service reputation.	Thank you for your feedback. A decision has been taken that vexatious complaints should not be included in the list of complaints that cannot be made. This decision was taken to ensure that the complaints arrangements are fair and open to all and in order to not discourage people from complaining. However, operationally, procedures for being able to dismiss vexatious complaint will be set out by the service providers and the Ombudsman body.
Really important to have this available and agree focus should not be on monetary consequences by improving services. Also think there needs to be a culture of owning up to mistakes and sharing information with service users if any issues occur.	Thank you for your feedback, which the Department agrees with. In relation to the culture of owning up to mistakes - legislation to require this was brought into force in April 2021. This was as part of the Manx Care Act 2021 and the Manx Care (Duty of Candour Procedure) Regulations 2021.
It's particularly important that there's an effective and useable complaints system in place for mental health patient service users / people with high functioning autism. I've been in situations in the past where I've been dealt with inappropriately / disrespectfully, and it's caused considerable distress and a phobia of being seen by mental health services again. This means I'm getting no care at all, besides medications already in place.	We are sorry to hear this and agreed that it is important that there's an effective and useable complaints system in place for everyone. The proposals require more signposting to support services such as MCALs and independent advocacy services that may help people with such issues to make a complaint.

Within the responses received, there were 5 main elements related to the following themes:

1 Supportive of the proposals (28.6%)
2 Importance of supporting and training staff (17.1%)
3 Not supportive of the proposals (8.6%)
4 Consultation was too long (5.7%)
5 Other, including: (28.6%)
- Separation from politics
- Respecting powers of the IRB
- Transparency
- Culture of accountability
- Local level resolution

Appendix 3

Complaints Modernisation Part 1 - Breakdown of Written Responses

Please note that only responses with permission to publish are listed within the tables however all responses are factored into the main themes identified.

Topic	Feedback to consultation	DHSC response
An independent adjudicator or ombudsman to replace the IRB	The inclusion of all health care providers including private would be welcomed.	We do not have the vires for this in the current primary legislation but it will be considered as part of the Reform Bill.
An independent adjudicator or ombudsman to replace the IRB	"[*redacted*] strongly supports the option of having a stand-alone ombudsman as a separate legal entity. Whether recruitment should be on Island or via the UK Ombudsman's Association is a matter for debate when weighing accessibility and cost against independence. We would not support the options of extending the remit of the Tynwald Commissioner or of the DHSC assuming responsibility for this role in a regulatory capacity."	Noted, this will be considered as part of the Reform Bill.
Structure and makeup of IRB	"A single IRB must be the way forward as it takes away complexity and saves time as well as simplifying training and expectations. We are concerned that this has not been addressed much earlier than now." "In regards training for IRB; "Of the options for addressing training we all agree that the second option of IRB members having CPD hours would provide more flexibility and better training pathways, with consequential likelihood of improved compliance. Members of IRB must be competent as a result of relevant training."	The DHSC and Ombudsman body together will decide on what is relevant and appropriate in relation to its training. The DHSC intends to issue guidance on the operation of the Ombudsman body including the amount and type of training it considers appropriate.
An independent adjudicator or ombudsman to replace the IRB	"[*redacted*] is in favour, in the longer term, of an Independent Ombudsman, independent from the DHSC, that reports direct to Tynwald and that such a body should cover both Departmental services and Private services."	Noted, this will be considered as part of the Reform Bill.
Alternative suggestions for investigating/reviewing complaints	"Actually there are 4 options not 3 - Ombudsman should be contracted from UK ombudsman assn so entirely independent. Private included-Yes Review whether processes correctly followed and verdict correct. Should be ombudsman trained with legal and medical experience. Reports to holder of complaint -DHSC or Manx care who share it with Minister/Tynwald Gov contract to external provider for a binding decision on process and verdict."	Noted, this will be considered as part of the Reform Bill.

Structure and makeup of IRB	• The Commission feels that the number of members should reflect how the Department wish the IRB to operate not simply be based on the sum of the existing. The nine members proposed is a good transitional arrangement which will suit the Commission as it simplifies the change but is it the best arrangement long term? • 'Recognised qualification' needs an interpretation as the SSIRB already has. The Commission would suggest there being an upper limit on the number of appointees with a 'recognised qualification' to avoid the body being dominated by professionals as opposed to those with the skills, knowledge and experience to meet the person spec • The Commission disagrees with the concept of appointing from outside the Island. It believes there is a sufficient pool of capable people on the island • The Commission fully supports the 'Training' item which should include a core mandatory training programme for new appointees determined in advance, with any additional individual training needs determined by the members themselves, also to be funded.	Thank you for your responses. The Regulations will give some flexibility to the number of appointments depending on the workload. It is not currently possible to determine the expected workload for the information that the Department has. The staffing will be reviewed as part of the arrangements to enhance the Ombudsman under the Reform Bill. It is planned that the qualifications needed for members are defined within Regulations. The requirement is that at least one member is qualified in health and at least one member is a social worker (or recently required social worker). The other members must have a balance of experience as the Appointments Commission feels appropriate. The other comments have been noted. In relation to the concept of appointing from outside the Island, the Department has decided to remove the paragraph that would prohibit appointing people from outside the Island to allow this to be considered, if it is required.
An independent adjudicator or ombudsman to replace the IRB	Over Due. Has to be established as a body corporate. Has to be separate from government, public declarations attesting too no conflicts of interest. If a conflict of interest is identified, remedies to have equivalency too private corporations under companies acts. A Public Hansard of all discussions has to be freely and easily available, on the Web. Separate agreed budget to be agreed and ring fenced so no undue budgetary pressure can be applied to this overseeing body. Constituents of overseeing body to have a maximum term, say not more than 5yrs, no return to the body corporate. Officers and body corporate to be indemnified from prosecution. Body Corporate to have powers to bring legal actions against IOM Gov, members of, or civil servants. Cost of actions met from IOM Gov Public purse, not from the overseeing bodies budget.	Thank you for your comments, which have been considered. In the short term the Department has decided to set up an Ombudsman body. In the future, under the Reform Bill, this Ombudsman will be enhanced so that it is more independent of Government. It is likely to be set up as a statutory board rather than a body corporate; however, this requires further consideration and the final proposal will again be subject to public consultation.

Structure and makeup of IRB	Health & Care Independent Review Body. (we can call it the Health and Care Ombudsman Scheme) An Independent Review Body (IRB) is established. It shall consist of (6) members appointed for terms of 5 years by the Appointments Commission The members of the IRB shall elect a Chair and Deputy Chair. Members of the IRB will be remunerated under the Payment of Members legislation using an analogous scheme to that applicable to the Financial Services Ombudsman Scheme. The IRB shall investigate complaints about delivery of health and care services by Manx Care and health and care service providers contracted to provide health and care services by the DHSC and Manx Care. The IRB will only investigate complaints which have not been resolved by local resolution processes between the complainant and the service provider. Any complaint received which has not been the subject of a full local resolution process will be referred back to the service provider with, if necessary, steps to be taken by the complainant and service provider within a stipulated timeframe. Any part of the complaint raised by the complainant to the IRB which was not the subject of the complaint to the service provider for local resolution will not be investigated by the IRB. Each complaint shall be allocated to an adjudicator. Complaints will normally be investigated on paper. In exceptional circumstances the adjudicator may determine, in the interests of justice and transparency, to hold an investigation with parties and witnesses present. Investigations shall be conducted in accordance with the rules of natural justice and human rights principles. The overriding objective as set out in the Rules of the High Court 2009 will also apply. The IRB may find a complaint upheld or not upheld. The IRB may make recommendations to Manx Care, service providers and DHSC about standard of service provision, suggested improvements but shall not act as a disciplinary body.	Thank you for your comments which have been considered in relation to the way the proposed Ombudsman should operate and how this should be communicated to the public. It is for the Ombudsman body to set the process for how it will review complaints, within the confines of the Regulations. The Ombudsman body will be required to issue a code of practice for how it will handle complaints made to it, which should be set out in plain English.

	IRB is not entitled to uphold complaints which are purely about Manx Care or DHSC policy. IRB may (may not) award compensation if it believes it appropriate. If either the complainant or service provider is dissatisfied by the IRB investigation outcome they may apply to the IRB in writing within 21 days for a review by the same adjudicator. If, after a review, either the complainant or service provider is still dissatisfied by the IRB investigation they may apply to the IRB in writing within 21 days for a final review by a different adjudicator. You can publish, no need to anonymise I'm also senior financial services ombudsman. We are implementing guidance for service users, and adjudicators, in plain English.	
Complaints to be made by others	Consider whether we can include anything within the Regulations or the Reform Bill to allow a mechanism to be found (by whatever name) to allow people that are aware of an issue but have not been directly impacted by an issue (such coroner, MHKs, Tribunal Chairs) to point out poor practise to the Department or Manx Care and to ensure that it is looked into and learnt from.	Thank you for your comment. After consideration, the Department does not believe that the mechanism that has been suggested should form a part of the complaints arrangements. Complaints should be raised by the person that has been impacted by the issue (or their representative). As part of the Department's assurance process, it will horizon scan within the public domain (including coroners and available tribunal reports). However, an assurance process cannot be put in place in relation to things that that are outwith the Department's legal vires.
MCALS / Independent Advocacy	[*Redacted*] notes the introduction of the MCALS which is now operational and has been welcomed and used by the public. We strongly support the intent to include advice on HOW to complain as part of the MCALS service. We also note that further clarity has been provided about the meaning and distinctive nature of 'Advocacy', although we understand that this service has still not started. The [*redacted*] strongly supports the proposal to have a single integrated and time bound complaints policy and process. We support the idea of including all providers (Manx Care, its Contractors and private providers).	Thank you for your comments.
Skills/experience of IRB members	[*Redacted*] believes that a single combined IRB should be swiftly enabled, and that it should not only include Social Care but eventually Mental Health Services (see part 2); that it should include both Social Care and Health Care professionals; and that appropriate training should be given to all members. We would like to see further details of what might be defined as 'appropriate' and which skills/experience will be required for IRB	Thank you for your comments. It will be for the Ombudsman body and the DHSC to work together to define an initial induction training pack of the group followed by additional training for individual members. It will be difficult to define this until the members have been appointed. In term so of the experience, it will be for the Appointments Commission to determine although the

	applicants. We would not support an assumption that existing IRB members of both services would be an ideal mix of skills and experience in the combined IRB.	Regulations will require that the body must include at least one health professional, at least one social worker, and a mixture of other people experienced in health, social care, legal matters, dispute resolution and administrative justice.
IRB time limit for complaint submissions	Whilst we understand that international best practice may be to accept complaints up to 12 months after the issue was identified, we would support consideration of keeping the time limit to 6 months. Some members believe that this should be strictly adhered to so that time frames are as tight as possible. We acknowledge that there may be evidence of which we are unaware that explains why 12 months is better and recognised internationally. Other timescales seem sensible and logical, as is retention of the IRB decision being final.	Sometimes people are distressed or do not become aware of issues straight away. The extension of the time limit for making a complaint is to give people sufficient time to make a complaint and does not impact upon how quickly the complaint must be dealt with once it is received.
Investigating complaints when legal action has been threatened or taken	We strongly support the proposal that investigations should continue regardless of whether legal action has been signalled (whilst accepting the examples where exceptions may be needed).	Noted
Timescales for responding to complaints	We support the notion of informal verbal resolution with 3 days (that would not be logged as a complaint); however we also believe that once a complaint is logged, even informally, it should be put in writing at the time, for the avoidance of future doubt. This could be included in the Regulations which already propose specifying a written response. Along with general agreement that there should be a requirement to bring regulatory review that ensures best practice, there was a strong belief amongst members that timescales should be specified and kept as short as possible; and that time should be made of the essence. We are aware of past cases that could have been resolved so much more quickly if prescribed timescales had been correctly aligned with appropriate information logging and sharing.	Any complaints that are logged as complaints must be put in writing, so for example, if a complaint was raised informally and not dealt with within 3 working days then this should be logged and dealt with as a formal complaint.
Training for those dealing with complaints	Ongoing training for those involved with complaints at all levels received our support. We would like to know how the training will be provided, by whom, and to what standard. We are keen to see validated qualification/ competence/ experience for relevant people at all levels but we would also like to know HOW these are going to be required in legislation.	This detail will be for each service provider to decide but it will be part of what is required to be reported to the Department so that the Department can assure itself that services are improving as a result of complaints received.
General feedback on Consultation presentation	DHSC members have previously acknowledged that consultations on the IOMG Consultation Hub can be perceived as off-putting, full of words and high-brow content. The website itself can seem obscure. We advocate a better approach to getting information into peoples' line of sight day to day including more media coverage using platforms that most people see, allowing the capture of unfettered comments of those with genuine concerns. The IOMG's own code of practice on	Thank you for your comments which the Department feels are fair. It is the Government's policy to publish its consultations through the IOMG Consultation Hub, but this does not have to be the only means of consulting. In relation to this pair of consultations, the detail of the legislation is very complicated and thought was given to how to present the information in a way that is understandable for the public. It

	consultation states that: 5) We provide jargon free and understandable information. 6) Use suitable methods to deliver the consultation. This particular pair of consultations is particularly pertinent to the paragraph above because, as one [*redacted*] said, 'Complaints legislation reform is at the heart of cultural transformation'. Communications have so far been low key - this could be a lost opportunity. We are concerned that the consultations potentially open the door to lack of trust by respondents because they tacitly imply a failed system. Therefore any response to the consultation will need careful handling to prevent trust in delivery being further undermined.	was advertised by social media; however, consideration will be given in future to additional engagement to ensure that consultations are getting information into peoples' line of sight. Additionally, the consultation was being carried out during the purdah period, which is unusual but was considered necessary in this situation to get engagement in order for this work to progress.
Complaints to the IRB	Escalation to the IRB should be after 3 months rather than 6 months.	Agreed, the timescale for escalating a complaint to the ombudsman body has been reduced within the draft Regulations.
Who they apply to	Ensure that "services" only include health and social care services not other services (I.T, equipment maintenance etc.)	Thank you for your comment. This will be clarified in the Regulations.
Who they apply to	From a practical perspective it would be easier if the proposed regulations covered both ROCA registered entities and any person or body providing services to MC to avoid there being 2 sets of regs trying to cover the same issue/s…	This is not feasible because not all Registration of Care Act 2003 ("ROCA") registered entities provide health or social care services. ROCA applies a minimum standard and these Regulations provide additional requirements on those that provide NHS and social care services under the mandate to Manx Care.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 2 - Respondent would like to see these implemented immediately	Noted, but consideration needs to be given to the practicality of the implementation reaching a balance between bringing in the new requirements as soon as possible and giving sufficient time for the set up of the new Ombudsman body and a transitional period for the new procedures to be implemented by all service providers (including some that have not previously had a statutory requirement for complaints arrangements). It is proposed that the Regulations will come into operation in October 2022.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 3 - Will the secretary be employed and subject to IOM Government code of conduct? Why can't the IRB start employing their own staff without interference?	The current proposal is that the secretary will be employed by the Public Services Commission to give some independence from the DHSC but still be required to operate under the Government Code of Conduct. The secretary will operate under the advice of the Ombudsman body.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 4(3) - Respondent does not think persons referred to in section 26(I)(b) must hold a qualification that would enable a person to practices as (a) Nurse, (b) an occupational therapist, (c) a psychologist, (d) a psychotherapist (e) a social care worker or (f) a social worker. Instead the respondent would like them to hold a qualification as a Doctor.	This list is taken from the requirements for the current Social Services IRB and seeks to cover qualifications that would allow a person to have experience of and advise on social services complaints. It is not appropriate for all the experienced people on the IRB to be doctors as complaints will be across the whole of health and social care services. This list

		will be reduced to just social worker to ensure that the right social work experience is present within the membership.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 3 (4) - Respondent believes 'health care professional' is too wide. Respondent thinks it should be a clinician as outlined in 33/06.	The term clinician is not defined in legislation and could be too narrow to capture the range of professionals that work within the health service. The term is defined within the Health Care Professionals Act 2014 and covers only registered health professionals: (a) a registered medical practitioner; (b) a fully registered chiropractor; (c) a fully registered osteopath; (d) a member of the profession of nursing or midwifery who is a registrant; or (e) a relevant professional who is a registered professional (defined in the UK Health Professions Order);
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 5 - Respondent does not think 'the department' needs to be included. The respondent believes the IRB are meant to be independent of the department, the department should be not involved at all. As professionals, the IRB should be more than capable of knowing what their training requirements are.	The Ombudsman body must be independent of the organisations that are providing the services that may be complained about. Since the separation of the Department from Manx Care, the Department no longer provides services so it is considered that the Ombudsman body does not need to be completely separated from the Department in order for it to be independent. The Department will provide the funding for the training and so it does have a role in considering what training is appropriate for it to fund.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 5 - Respondent would like to see the IRB include details of their training in their annual report	A change will be made to the Regulations to ensure that details of the training undertaken is set out within the Ombudsman body's annual report.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 5 - Respondent would like each member of the IRB to complete no less than 5 hours training per annum.	This will be added to the guidance that is issued by the Department in relation to the operation of the Ombudsman body.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 5 (2) - Respondent has scored out 'Department' twice and suggests the IRB agree an annual budget with the Treasury to retain independence.	The Ombudsman body must be independent of the organisations that are providing the services that may be complained about. Since the separation of the Department from Manx Care, the Department no longer provides services so it is considered that the Ombudsman body does not need to be completely separated from the Department in order for it to be independent. For the interim solution it is considered that this position is adequate. However, it is intended that the independence of the Ombudsman body will be increased under the

		proposals to be set out within the Reform Bill.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 6 (4) Who do the Public complain to about IRB actions regarding their employment? Same questions as secretary, are they employed etc.?	The Appointments Commission can consider complaints made about the actions of the Ombudsman body members. Ombudsman body members are not employed but appointed to the body.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 7 (1)(a) - Respondent would like to see this done in writing.	The Ombudsman body members will be required to declare conflicts of interest to the parties to the proceedings and not take any further part in reviewing a specific complaint unless all parties agree that it is appropriate for the member to continue reviewing the complaint. The Department does not think that it is a good idea to make this public in all cases as we expect that many conflicts would arise from a person's former involvement with the person making a complaint or on their behalf. Some conflicts may be personal in nature and also some conflicts might arise in "real time".
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 7(1)(ii) - including the IRB secretary	The Ombudsman body secretary, as a public services commission appointment, will be required to comply with the Government staff guidance in relation to conflicts of interest which requires that the person's line manager is made aware of any potential issue where there could be an actual, or perceived, conflict of interest.
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 7 (2) - Respondent would like to see this in writing	Noted
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Regulation 7 - Respondent would like to see the following things added to Regulation 7: (3) Members of the IRB shall ensure that the IRB are independent of Government, DHSC and Manx Care. This will including using professional independent advisors outside the Government, DHSC and Manx Care to ensure that the role of the IRB is truly independent and that no conflict issue arises (i.e. no Chinese walls with the Director of Public Health providing independent medical advice or the AG providing independent legal advice etc. etc. (4) Within 5 day of receiving a written notification of a potential conflict of interest or duty, the Secretary will record the potential conflict in a Register and confirm, in writing to all parties, that the notification of potential conflict has been recorded and that there is 14 days to resolve the issue. (5) A conflict of interest or duty notification	This detail is not appropriate to be contained with the Regulations. The Ombudsman body will be required manage any potential conflicts of interest within their meetings as appropriate. The draft Health and Social Services Ombudsman Body (Constitution, etc.) Regulations 2021, along with the Government Code, provide sufficient detail on how conflicts should be treated. The Ombudsman body must be independent of the organisations providing services about which it may be require to review complaints. Since April 2021, the Department no longer provides health or social care services and so it is considered acceptable for this interim Ombudsman body not to be totally independent of the Department.

	must be resolved within 14 days. If the conflict of interest or duty notification is not resolved within 30 days then the IRB must lay a report before Tynwald immediately. (5) Any member of the public may report a potential conflict of interest or duty to the Governor of the IRB. The same rules above apply in relation to the treatment of potential conflicts. (6) The register detailing conflicts of interest or duty shall be maintained by the Secretary, record the date the conflict issue was raised, the parties, issue and details of the outcome. The Register shall be open to inspection by any member of the Public. (7) If a Complainant or Member of the public is not satisfied with the outcome of the notification, then they may report same to the Tynwald Commissioner for Administration who may review the details and make the final decision as to conflict. (8) If any member of the IRB fails to report a potential conflict of interest or duty then this will be viewed as gross misconduct. (9) The IRB will provide a copy of the Conflict of Interest or Duty Register each year in their annual report with the name of any individual redacted.	
Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021	Footnotes on 'Health and Social Services Independent Review Body' Respondent has asked, What type of statutory body?	Statutory body just means a body that is set up by statute. Its constitution is set out within law.
National Health Service (Complaints) Regulations 2021	Footnotes on Secretary - Respondent wants to know, are they employed, is so by who? How are their services recharged?	It is proposed that the secretary is employed by the public services commission and paid by the Department. This is considered appropriate as it is aligned with the position of staff appointed to tribunals under the Tribunals Act 2006. Since April 2021, the Department no longer provides health or social care services and so it is considered acceptable for this interim Ombudsman body not to be totally independent of the Department.
National Health Service (Complaints) Regulations 2021	Regulation 4(2)(g) - Respondent would like to see the complainant advised of the action taken in light of the complaint.	The complainant would be advised within the response to the complaint. This requirement is contained within the draft Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 4(2)(i) - Respondent would like do see an apology provided in writing, where appropriate .	There is a requirement for this to be included within the response to the complaint under the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 4(2)(j) - the respondent would like to see the complainant educated on Duty of Candour.	Within the Manx Care (Duty of Candour) Regulations 2021, the duty of candour process must be publicised by the service provider. It is not possible within the scope of the Regulations to be able to set out additional requirements in relation to duty of candour. However, the Department will outline within its

		guidance that people should be advised about duty of candour processes if the complaint raised is in relation to harm caused to an individual.
National Health Service (Complaints) Regulations 2021	Regulation 4(3) - What about people with reading difficulties? What about publicity for complaint arrangements? Everything should be available online, policy, procedures etc.	Publicity for the complaints arrangements is covered under the draft Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 5(6)(c) - Respondent would like do know who checks clause A,B and C for the IRB in relation to complaints about their behaviour?	This regulation is in relation to a service provider not the Ombudsman body. The Ombudsman body members will be appointed by the Appointments Committee who will check and appoint based on experience.
Structure and make up of the IRB	1. Why have Doctors been excluded from the membership? 2. Should there be a maximum number of members on the review body with a health or social care related qualification? The Department may like to refer to the Legal Aid Committee constitution. 3. In the document Health and Social Services Independent Review Body (Constitution, ETC.) Regulations 2021 it appears section 4.4 under 'Membership and composition' is duplicated and is already covered in section 4.3. 4. It appears that the Health and Social Services Independent Review Body (Constitution, etc.) Regulations 2021 is attempting to introduce additional requirements which are not covered by the amendment to the primary legislation. Social Services Act 2011 (Section 26) (Amendment) Regulations 2021 26A (1) (b). The constitution relations specify 'at least one of the 8 persons referred to in section 26A (1) (b) of the Social Services Act 2011 must be a health care professional'. This regulation appears to try and over rides that which is given in the primary act. If the Department wish to add this criteria then it should be as a recommendation to the AC who are tasked by the Primary Legislation to determine the relevant experience. The AC would then set that as Policy which would give flexibility in the event of difficulty finding suitably 'qualified' candidates. 5. The way in which the body is currently constituted it doesn't allow the Appointments Commission any discretion to appointment additional members if the workload cannot be met. 6. In the longer term; a. If an independent adjudicator/ombudsman was appointed what type of appointment would it be? b. Would the appointment be on a full time employment basis and how many people would be appointed? c. What is the value to government over having an Independent Review Body? d. if implemented how will the effectiveness and 'value for money' compared to the IRB be	1. Doctors have not been excluded from membership, they are captured within the definition of health care professional. 2. DHSC has not determined a maximum number of members with such qualifications. It will be for the Appointments Commission to appoint the right balance of members as it sees fit. 3. The definitions of persons are different for the social services professional and the health care professional. 4. The primary legislation allows for such regulations to be made. The policy aim is that at least 1 member of the Ombudsman is a social worker and 1 is a health care professional. The remaining balance can be determined by the Appointments Commission. 5. An amendment will be made to the proposed Regulations to allow such flexibility. 6. In the longer term, the Department's will consider an independent Ombudsman with the remit to review unresolved health and social care complaints to be set up as a statutory board, operationally independent from the Department and Manx Care or to appoint an individual to the position on Ombudsman. Further consultation on the Department's proposals will follow in due course.

	measured? e. Will it be a probationary service to be reviewed after the first year?	
Private patients access to IRB	If services were accessed privately what would the alternative route for those wishing to make a complaint be if they didn't use this body?	There is no route for complaints about private providers to be reviewed independently. Complaints would be made to the private provider and, if the complainant remained unhappy with the response, he or she could change provider.
Combining of the IRBs	The Appointments Commission is primarily concerned about how the constitution of the two independent review bodies will be combined given the vast difference in the two, and believes that it will be vital that this is set out prior to public consultation. Specifically, the Commission notes that the constitution of the Social Services IRB is set out in primary legislation rather than regulations. 1. If the independent review bodies are combined what impact will this have on workloads and the number of members required for the IRB? 2. The Commission notes the use of the term "convenor" in relation to the Health Services IRB. Such a role does not exist in the Social Services IRB. 3. What will the role of the Convenor be and how will a 'Convenor' be selected?	The Department has considered the responses to part 1 and part 2 of the Complaints Modernisation consultations, along with the practicality of setting up a new Independent Review Body for an interim period, and decided that it would be of greater benefit to the public to move towards setting up an Ombudsman at the earliest opportunity. As a result, the Health and Social Care Ombudsman Body is proposed within the revised Regulations.
AC's right to appoint members to the IRB	The document seems to indicate that the Appointments Commission (AC) would have a role in making appointments to the combined IRB and it would offer the following benefits should this be the case: - It 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 - It has a systematic and consistent approach to appointing to independent bodies across all sectors across government - It is broadly familiar with candidates who typically put themselves forward for such appointments - It is a cost effective independent body - It has a diverse membership - It already has the responsibility of appointing to the Social Services Independent Review Body	Thank you for your comments, which the Department agrees with.
Structure and make up of the IRB	The document makes reference to drafting regulations for consultation on page 7, including inter alia membership requirements. The Commission would suggest, based on its experience, that details relating to what might be described as the "person specification" should not be set out in statute or regulations.	Agreed
Extent of IRB's remit	If the process is extended to cover all providers, what services are covered by the term 'private entities'? (private healthcare, nursing homes, etc. . . .)	This would be determined under the planned revisions to the Regulation of Care Act 2003.

Skills/Experience of IRB members	Experience leads the Commission to say that initial and ongoing training is essential and should be planned and funded for those appointed to this role.	Agreed
Remuneration of IRB members	A remuneration model will need to be considered to tie in with the commitment to this role	Agreed
Functionality of IRB	1. It will be important to understand the potential level of workload and therefore the size of the body should be reflect this 2. The AC feels it would be beneficial to have flow charts for the existing operation of both bodies to be able to consider the most effective parts of the process 3. Will executive/administrative resources be made available to enable the body to function? E.g. composing 'Standard considerations' for acceptance of a complaint, Annual Report, undertaking investigations, preparation of reports, minutes of meetings?	Agreed, the interim position will be left flexible to allow the membership of the Ombudsman body to grow or reduce as applicable. The workload will not be known until the framework is up and running as it will be better publicised, may be seen as more independent and therefore more useful, it will cover social services which have not been covered previously and there will be a longer timeframe in which to make a complaint. The interim position will be reviewed and learning taken from it to inform the longer solution.
IRB-related terminology	Reference to IRB/Independent Adjudicator/Convenor and other terminology/names throughout the document could be confusing for the public and may be better either standardising or explaining the difference.	Noted
Ombudsman Scheme	1. If the long term policy is to move to an Ombudsman scheme, will the combined IRB be seen as an interim measure, and if so for how long? 2. The Ombudsman scheme will presumably require 'full time employees'? Including Contracts of Employment which are outside the remit of the AC. However, there may be some advantage in employing the AC experience to identify and recommend. 3. The Ombudsman scheme would change the nature of the complaints process so if it does become a 'long term' policy, should the operation of the IRB be tailored towards this?	The Department has considered the responses to part 1 and part 2 of the Complaints Modernisation consultations, along with the practicality of setting up a new Independent Review Body for an interim period, and decided that it would be of greater benefit to the public to move towards setting up an Ombudsman at the earliest opportunity.
National Health Service (Complaints) Regulations 2021	Regulation 6(3) - The respondent disagrees with 'in the opinion of the complaints manager had or'. The respondent has asked for relative to be defined, What is the test for sufficient interest? What about charities? The respondent has stated, ' I have lived with my partner for 30 years, is he a 'relative?'	The Department agrees that this may not be an easy test to determine and so propose to change the wording in this section to refer to acting in someone's best interests, which is a common test used in relation to capacity.
National Health Service (Complaints) Regulations 2021	Regulation 6(4) - The respondent would like the representative may ask the Tynwald Commissioner for Administration to review the decision of the Complaints Manager.	The Tynwald Commissioner for Administration's remit does not cover reviewing complaints where there is already a mechanism for this to be reviewed by another body, which in this case would be the Ombudsman body.
National Health Service (Complaints) Regulations 2021	Regulation 8(1)(a) - Respondent believes this is too vague and would like more information to be provided.	This covers complaints that a service provider might have in relation to its contract with Manx Care which should not be progressed through Manx Care's complaints procedure but dealt with as a contractual issue.

National Health Service (Complaints) Regulations 2021	Regulation 8(1)(c) - The respondent disagrees with ' a complaint which (i) is made orally; and (ii) is received to the complainant's satisfaction not later than the end of the third working day after the day on which the complaint was made.' Respondent states that Oral complaints should be subject to regulation.	Oral complaints are required to be dealt with under the Regulations. This regulation allows 3 days for simple issues to be resolved by staff at the front line before they become formal complaints. However, your comment below in relation to staff thinking issues are resolved when they are not is noted and so consideration will be given to ensuring that a record of these is made so that they can be used as part of a formal complaint if the issue needs to be raised again.
National Health Service (Complaints) Regulations 2021	Regulation 8(1)(d) - The respondent disagrees with, ' 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).' The respondent has the concern, what if further medical issues arise after 3 days? It is very difficult on ward to make a complaint, it is likely you will nod agreement until you leave. In our case, the nurse was rude, asked by Sister to apologise then the same nurse came back at 6am the following day had another go. Mum was too afraid to make another complaint but Sister thought it was resolved. Sister did not make a record of the oral complaint in Mums medical records and should have done, any complaint oral or written has to be recorded in the medical record	Your comment is noted and we plan to remove this section.
National Health Service (Complaints) Regulations 2021	Regulation 8(1)(e)(iii) - Respondent disagrees with ' a relevant complaints procedure.' Respondent would like to see an example of a relevant complaints procedure, by who etc. Respondent has asked, What about complaints currently undergoing investigation? What will transition be for 2004 regulations etc.?	Your comments are noted and this will all be defined within the final version of the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 8(1)(f) - what about the deceased? there is no recourse with the Information Commissioner, only for the living people, this clause is unacceptable if dealing with records for the deceased (take it from someone that spent £4000 in legal fees getting the records they were entitled to). also for living people, you must state or advertise complaint recourse is the Information Commissioner.	GDPR only applies to living individuals so this paragraph cannot be made to apply to the deceased. Health records for the deceased can be accessed through the Access to Health Records and Reports Act 1993. The Department is considering extending this to also cover social care records, a review of this Act will be required to determine if the policy within it for health services could be extended to social services. This is proposed to be done as part of the Reform Bill. These Regulations are not the right place to sign post people with complaints about data subject access requests to the information commissioner but the DHSC will include this within their guidance to complainants.
National Health Service (Complaints) Regulations 2021	Regulation 8(1)(g) - Respondent would again like to see the Information Commissioner mentioned. The IRB are not subject to FOI requests, so no public access to information. What about access to Government information for the IRB?	These Regulations are not the right place to sign post people with complaints about freedom of information requests to the information commissioner but the DHSC could include this within their guidance to complainants. It is agreed that the IRB should be

		subject to FOI and this will be reflected within the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 8(1)(h) - Respondent does not agree with this clause. The words 'proposing to take.' - how does that help a complainant? particularly if no action is taken?	This regulation will be removed.
National Health Service (Complaints) Regulations 2021	Regulation 8(2) - Would like to see the words 'as soon as reasonably practicable' changed to 'within 28 days'.	A change is proposed so that the requirement is within 20 working days to match the complaint response.
National Health Service (Complaints) Regulations 2021	Regulation 9(2)(b) - Review the decision not to investigate, what happens? IRB and then Ombudsman in case maladministration?	The Ombudsman body can review the decision not to investigate.
National Health Service (Complaints) Regulations 2021	Regulation 10(2)(a) - Respondent would like to see added 'or staff member must make a written record of the complaint on a standard form.'	It is not planned that a standard form will be required for making a complaint (as the Department does not wish to put any barriers in the way of people making a complaint); however, a standard form will be prepared, available for use and recommended in the Department's guidance.
National Health Service (Complaints) Regulations 2021	Regulation 10(2)(b) - Respondent would like staff member included as well as complaints manager. e.g. staff on wards, reception etc. on a standard form.	The complaints manager's role is defined in the Regulations. A person should be allowed to make a complaints to any staff member of a service provider (not just the complaints manager) but the complaints manager should remain responsible for documenting this.
National Health Service (Complaints) Regulations 2021	Regulation 10(2)(c) - The respondent would like to see the standard form be available for download on the website.	Agreed that the form should be available but that level of detail will not be explicitly stated within the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 10(2)(e) - Respondent would like to see that the Complaints manager will ensure that assistance is given to the complainant to provide further information. The respondent has stated concerns such as, how can you expect the public (as in my case) to review complex medical records? How do the bereaved, elderly, depressed etc., do this without help? Did the IRB Governor draft this clause?	This paragraph is only in relation to complaints that are made without sufficient detail to be considered. Complainants should not be asked to review complex records, the service provider should already have these records and so they should not be requested from the complainant. Complainants will be able to be supported by an independent advocate provided by the independent advocacy service, if they need help understanding and responding to requests from the service provider.
National Health Service (Complaints) Regulations 2021	Regulation 10(2)(f) - Respondent would like to see details for IOMHCA and Duty of Candour Policy to be provided.	Thank you for your response. A more general statement that any other relevant written guidance should be provided. The Department will signpost to these specific areas within their guidance.
National Health Service (Complaints) Regulations 2021	Regulation 11(1)(b) - Respondent would like on a regular basis to be changed to meaningful updated every 14 days.	Every 14 days may not be appropriate in all case so this has been left open for the complaints manager to negotiate a new timeframe with the complainant.
National Health Service (Complaints) Regulations 2021	Regulation 11(2) - Respondent would like to see this within a timescale of within 7 days.	Agreed that timescales should be included to stop any delays in meeting with the complainant. We will include wording to clarify that the meeting should be held within the 20 day period for considering a complaint.

National Health Service (Complaints) Regulations 2021	Regulation 11(2)(b) - Respondent would like ' a relevant health or social care professional' to be changed to 'a clinicians' as per 1d- 33/06. Respondent has stated that clinicians are regulated, officers workers who may be called professionals may not be regulated by a professional body. Please define 'clinicians' in definitions, i.e. a qualified reason regulated by a professional body.	Health or social care professional will be a defined term that covers those that provide services, not office workers. Clinician is a health focussed term and these Regulations are designed to apply to both health and social care equally.
National Health Service (Complaints) Regulations 2021	Regulation 11(2)(c) - Respondent would like such meetings to be offered no later than 14 days after (a) above. Respondent does not want to wait 4 months for a meeting then to be told a week before qualified staff are now not available is unacceptable.	Agreed that timescales should be included to stop any delays in meeting with the complainant. We will include wording to clarify that the meeting should be held within the 20 day period for considering a complaint.
National Health Service (Complaints) Regulations 2021	Regulation 11(6)(a) - Respondent would like to see if this happen if the complaint has not been finalised within 6 months.	The response letter would not be an appropriate place to notify the complainant of the ability to refer to complaint to the Ombudsman if it has not been finalised within 6 months (as they would not receive this letter until the investigation is concluded and the response is sent, which in this scenario would be later than 6 months). The Department will give guidance on when a complaint can be referred to the Ombudsman (which will include if a complaint has not been responded to by the service provider within 3 months).
National Health Service (Complaints) Regulations 2021	Regulation 11(6)(c) - Respondent would like this to state. 'provide details of professional bodies which may regulate the subject of the complaint.'	There is a requirement that the service provider must refer the complaint to the professional's regulated body if that is appropriate. The Department will give guidance to complainants on other routes that are available to them to raise complaints.
National Health Service (Complaints) Regulations 2021	Regulation 11(6)(d) - Respondent would like this to state, ' provide an apology for the delay.'	This will not be contained within the Regulations but it is an expectation and the Department will issue guidance that states this.
National Health Service (Complaints) Regulations 2021	Regulation 12(a) - Respondent would like to see this take place within 1 month instead of promptly.	It is impossible to say what the action will be in which case it is difficult to set a timescale that works for all situations. However, the letter to the respondent will be required to set out the timescales that the service provider has taken or will take the action proposed.
National Health Service (Complaints) Regulations 2021	Regulation 12(d) - Respondent would like the removal of the words, 'appropriate' and 'to send'. Respondent would like to this clause to be about 'all' complainants and to include sending a feedback form with the final response.	The Department does not wish to state how feedback must be gained from complainants - it is for the individual service provider to determine this in the best way for the people using their services.
National Health Service (Complaints) Regulations 2021	Regulation 12(e) - Respondent would like this clause to state, ' The feedback forms should be analysed by the complaints manager and reported on in the annual public complaints report prepared by the Department.	The Department does not wish to state how feedback must be gained from complainants - it is for the individual service provider to determine this in the best way for the people using their services.

National Health Service (Complaints) Regulations 2021	Regulation 12(f) - Respondent would like to add to this clause that the results of the reviews in the annual complaint report be published.	The outcome will be reported publicly by the professional body; therefore, it is not proposed that details of the case need to be duplicated in the reporting of the service provider. However, it may be of public interest to know how many complaints have been referred to a professional body by each service provider.
National Health Service (Complaints) Regulations 2021	Regulation 12(e) - Respondent would like this clause to state, 'and publish the results of reviews in the annual complaint report'.	This should be required as part of the duty of candour reporting and will be picked up in the next review of the Manx Care (Duty of Candour Procedure) Regulations which is planned to be within the next 2 years.
National Health Service (Complaints) Regulations 2021	Regulation 13(3) - Respondent would like Manx Care to operate an 'independent' advice and liaison service.	Manx Care are being required here to operate an internal advice and liaison service - it will put MCALS on a statutory footing.
National Health Service (Complaints) Regulations 2021	Regulation 13(d) - Respondent would like this clause to read, 'The service should be available during normal working hours, and by contactable by phone, letter, email and in person. The Department should employ adequately trained staff and ensure they are qualified to deal with complainants and understand equality, disability and access issues. The Department will ensure that access to the system will be for all and kept up to date in line with modern standards.'	It is for Manx Care to determine how the service should be operated. The suggestions for its operation provided during the consultation have been passed to MCALs for inclusion in consideration to how the service should develop after the initial trial period.
National Health Service (Complaints) Regulations 2021	Regulation 14(2)(e) - Respondent would like the addition of the word 'each complaint', rather than 'complaints' as a stand alone word.	It is not considered that this level of detail is necessary within the Regulations
National Health Service (Complaints) Regulations 2021	Regulation 14(2)(f) - The respondent has expressed that this would mean that the IRB recommendation can again be ignored. The respondent believes that this is unacceptable and failure to follow IRB recommendations should be reported to Tynwald on each and every occasion within 30 days.	The Ombudsman body's recommendations cannot be ignored as they will be required to be responded to by Manx Care and actions monitored by the Department. Within the monitoring, it should be reported where action has not yet been taken (with the reasons why not) so that these actions can continue to be monitored.
National Health Service (Complaints) Regulations 2021	Regulation 14(3) - Respondent would like to see this within 2 months instead of 3 months.	Timescales are to be reviewed as service providers (other than Manx Care are also to be required to report).
National Health Service (Complaints) Regulations 2021	Regulation 15(2) - Respondent wants the phrase ' as soon as practicable' to stop being used, stating that other Government Departments have timescales, as should DHSC/Manx Care. Instead the respondent would like to see this report which they have changed to 'annual' report to be laid before Tynwald 'by the 30th September every year and published on the Manx Care/DHSC website.	As soon as practicable is used to mean at the next sitting after it has been prepared. However, it is planned to state that reports should be submitted to the November sitting of Tynwald, which is the first available sitting after 30 September as documents are required to be submitted for the November sitting on 5 October. It is agreed that the report should also be published on the DHSC website.
National Health Service (Complaints) Regulations 2021	Regulation 16 - should include 'IRB' or service provider. Respondent does not think this should be face to face as it excludes staff that may receive complaints by telephone or email etc.	This section is only applicable to service providers so it should not state Ombudsman body. Ombudsman body member training is covered under the Health and Social Services Ombudsman

		Body (Constitution, etc.) Regulations 2021. It is agreed that face to face should be removed.
National Health Service (Complaints) Regulations 2021	Regulation 16(b)(ii) - Respondent has stated that the IRB have published and given out incorrect information previously.	Thank you for drawing this to our attention.
National Health Service (Complaints) Regulations 2021	Regulation 17(3) - respondent believes 'in the opinion of the Health and Social Services Independent Review Body had, or' should be removed.	The Regulations must set out who can decide whether or not the complaint has been made by an appropriate person, and for complaints to the Ombudsman body this should be the Ombudsman body members themselves.
National Health Service (Complaints) Regulations 2021	Regulation 17(4)(b) - what's are the tests for this? Respondent also wants to know if it can be appealed?	A change will be made to the Regulations to remove the limitations on who can be a person's representative (so that relatives are not expressly mentioned) and focus on whether the representative is conducting the complaint in the best interests of the person on whose behalf the complaint is made. A best interest decision is a decision made by applying the Best Interest principle, as set out in the UK's Mental Capacity Act 2005.
National Health Service (Complaints) Regulations 2021	Regulation 19(a) - Where is the form? What about help with the form for those struggling with literacy or disability?	The form will be published by the Ombudsman body as part of the implementation of the Regulations. Complaints will be able to be made orally or by a person's representative for those struggling with literacy or disability.
National Health Service (Complaints) Regulations 2021	Regulation 19(3)(b) - Respondent feels like this is petty. if a letter has all the information the IRB don't need to back to go back to the complainant, possible bereaved with a box ticking exercise or at the very least complete it and meet the complainant, some discretion required.	A letter will be accepted and this will be clarified in the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 19(4)(b) - Respondent suggests that all enquiries and complaints shall be recorded in the IRB register and numbered consecutively	This is operational detail that will not be stated in the Regulations but will be considered as part of the guidance to be issued to the Ombudsman body in relation to its operation.
National Health Service (Complaints) Regulations 2021	Regulation 19(5) - respondent has added, '(5) The Secretary must offer the opportunity to meet the Clerk to the IRB if the Complainant wishes to discuss he nature of the complaint, the remit of the IRB and presentation of the case the Convenor (Recommendation 2b of 33/06) such meeting to take place within 14 days.'	This is already covered under regulation 22. Fourteen days is considered to be too short a period but a timescale of 20 days for the complaint to be assessed (including meeting with the complainant) will be included within the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 20(2) - Respondent wonders if this can be appealed? The respondent has stated that surely this should be a convenor 1 and 2 procedure, not up to a chairpersons. Prefer Tynwald Ombudsman to review.	This paragraph has been included to give additional flexibility to the timescales for making a complaint (that have already been extended considerably within the proposals) in exceptional circumstances. It remains the Department's view that the chairperson of the Ombudsman body is best placed to decide this fact. If the complainant does not believe that a fair decision has been taken, this could be

		raised with the Ombudsman body through its corporate complaints process.
National Health Service (Complaints) Regulations 2021	Regulation 21(2) - Respondent disagrees with the words ' as soon as reasonably practicable,' and instead suggests that it should be within 14 days.	It is not considered necessary to put a timeframe on this.
National Health Service (Complaints) Regulations 2021	Regulation 22(1)- Respondent states this should be done within 14 days rather than 'on' receiving a complaint.	Fourteen days is considered to be too short a period but a timescale of 20 days for the complaint to be assessed (including meeting with the complainant) will be included within the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 22(1)(d) - Respondent believes that the standard considerations must be published and feels like the IRB cannot make it up as they go along.	The standard considerations are included within the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 22(2)(a) - Should be a 'Senior member' of the Health and Social Services independent Review body	Regulation 22 allows the meeting to be with any member of the Ombudsman body or the secretary (per recommendation 2 of the 2006 select committee on petitions for redress of grievance). This is considered to be the correct position as different members will have different experience which will relevant to specific complaints and so this allows the best member of the Ombudsman to meet with the complainant.
National Health Service (Complaints) Regulations 2021	Regulation 22(2)(b) - Disagrees with this clause	This will be retained as above
National Health Service (Complaints) Regulations 2021	Regulation 22(2)(c) - Disagrees with this	This will be retained as above
National Health Service (Complaints) Regulations 2021	Regulation 22(3) (Standard consideration B)- respondent wants to see added 'following a complete review of the file (recorded in writing). The respondent has stated how can they tell if they don't actually look at the complaint, as in my case?	The Ombudsman body members are required to review the complaint under the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 22(3)(Consideration E) - The respondent has asked is this is like GMC? Stating that the GMC has a 12 month timescale and complainants might be timed out. The respondent has asked for more detail regarding this.	Per the Interpretation Act 2015, enactment means Manx legislation so this would not mean complaining to the General Medical Council. An example would be a person detained under the Mental Health Act 1998 that wished to complain/appeal about the admission to a hospital for treatment under that Act. This would be reviewed by the Mental Health Tribunal rather than under these Complaints Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 22(3) (Standard consideration F) - The respondent would like more detail on this, like where?	An example of this would be complaints about mental health treatment that could be made to the Mental Health Commission under the Mental Health Act 1998.
National Health Service (Complaints) Regulations 2021	Regulation 22(3)(Standard consideration G) - The Respondent believes the words 'court or under' should not be included as they state, how can the IRB make this judgment regarding courts, they are not legally qualified.	Reference to the courts will be retained and a change will be made to require the Ombudsman body chair to be legally qualified.

National Health Service (Complaints) Regulations 2021	Regulation 22(5) - Respondent disagrees with the words ' as soon as practicable' and instead suggests that it should be within '14 days.'	Agreed, that it would be useful to have a fixed timescale here and so this change will be made.
National Health Service (Complaints) Regulations 2021	Regulation 22(6) - Respondent states that the decision must 'outline the IRB understanding of the complaint.'	Agreed
National Health Service (Complaints) Regulations 2021	Regulation 23 - where is the second convenor review and Ombudsman? nothing in the above appears to give the complainant an automatic right to a review.	The Ombudsman body will consist of a chairperson and various professional members. The term convenors will no longer be used. It will be for the Ombudsman body to set out how it will review complaints in a code of practice, which is intended to follow best practice as outlined by the Scottish Public Services Ombudsman, and its corporate complaints process to be followed if the complainant is not happy with how the review has been handled by the Ombudsman body. However, the Ombudsman body's decision in relation to the subject of the complaint will be final.
National Health Service (Complaints) Regulations 2021	Regulation 24 - Respondent believes the word 'decides' should be changed to ' is required.'	To make this change an explanation of the criteria in accordance with which we can determine whether the Ombudsman body is required to review the investigation of a complaint. It has been determined that this should be left for the Ombudsman body to determine and so no change will be made to the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 24(2)(b) - Respondent states that this was not done in their case, in fact it was used as an excuse for them not to bother looking at the complaint in detail despite providing numerous examples of errors or omissions in the DHSC response	Noted
National Health Service (Complaints) Regulations 2021	Regulation 24(3)(b) - Respondent disagreed with, 'is the subject of legal professional privilege.' Respondent asks, says who? When and what documentation is subject to legal privilege. What about standard legal disclosure rules? What if DHSC know there might be a legal case, can then claim privilege over relevant documentation and put the shutters up in an attempt to stop an investigation. You must define documents subject to legal privilege as documents between Advocates and their Client. Patient information is not subject to legal privilege.	Information subject to legal professional privilege is information that is confidential between a client and their legal advisor. Health records would not be subject to legal professional privilege.
National Health Service (Complaints) Regulations 2021	Regulation 23(5) - Respondent thinks this should be one month and not 6 weeks in line with standard SARs.	It is agreed that one calendar month, in line with GDPR SARs would be an appropriate timeframe for a response to be requested.
National Health Service (Complaints) Regulations 2021	Regulation 23(6)(a) - Respondent wants this to include the complainant	The information will have been requested by the Ombudsman body for the Ombudsman body's use and so the response should be to the Ombudsman body. It will be for the Ombudsman body to update the complainant on progress with its review.

National Health Service (Complaints) Regulations 2021	Regulation 23(6)(b) - Respondent would like to see this exceeding no more than two months, but only if a particularly complex case (in line with standard SARs). if the case is complex, the person or body must justify the complexity.	Agreed that a time limit aligned to GDPR SARs would be appropriate here.
National Health Service (Complaints) Regulations 2021	Regulation 23(6)(c) - The IRB should report failures in the provision of information by providers under normal SARs rules to the Complainant and offer to report the failure to the Information Commissioner. Any reports to the Information Commissioner shall be included in the IRB annual report	This data request would not be a DSAR and so there are no legal vires for this to be reported to the information Commissioner.
National Health Service (Complaints) Regulations 2021	Regulation 24(7) - Respondent would like this to include ' in accordance with generally accepted principles' rather than 'any manner which seems to it be appropriate' and that advice should be 'independent.'	It is not clear what is meant by generally accepted principles in this context. It is considered that the Ombudsman body should have the jurisdiction to determine how to conduct its reviews; therefore, this change will not be made. The Ombudsman body should be free to determine what additional advice is required, when reviewing a complaint. It is accepted that this advice should not be provided by a party that is connected to the complaint.
National Health Service (Complaints) Regulations 2021	Regulation 24(10)(d) - The respondent would like this to state, ' The complainant will have the right to attend any hearing and provide feedback via the IRB.'	This will not be set out within the Regulations but the Ombudsman body will be required to set out its procedure for reviewing complaints within a code of practice.
National Health Service (Complaints) Regulations 2021	Regulation 24(10)(e) - The respondent would like this to state, ' The party being complained about may be required by the IRB to attend and give evidence at an oral hearing.'	This will not be set out within the Regulations but the Ombudsman body will be required to set out its procedure for reviewing complaints within a code of practice.
National Health Service (Complaints) Regulations 2021	Regulation 24(11) - The respondent would like this to read, IRB 'must establish, operate and publish.' Respondent has asked where is it? this should have been provided as part of the consultation, the IRB have had 6 months to draft.	Agreed, that the complaints procedure should be published and the Regulations will be updated to explicitly require this. As the new Ombudsman body does not yet have a legal basis and so is not constituted, it has not yet produced its complaints procedure. This will be produced as part of the implementation of the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 25(1)(e) - Respondent would like this to state, 'any failure to provide a report within 6 months should be notified to Tynwald within 14 days.'	The interim Ombudsman body will not be accountable to Tynwald in this way; however, any reviews that have not been completed within 6 months will be reported to Tynwald on an annual basis.
National Health Service (Complaints) Regulations 2021	Regulation 25(5) - Respondent would like to see this happen within one month of issuing the report.	Agreed

National Health Service (Complaints) Regulations 2021	Regulation 25(6) - Respondent would like this to state, ' Recommendation 2c. 33/06 gave the complainant a right to meet the convenor following their decision.	Agreed that this was a recommendation within the 2006 select committee on petitions for redress of grievance; however, the Ombudsman body that is being set up will not consist of individual convenors. It will be for the Ombudsman body to set out its process for reviewing complaints, which is expected to follow best practice issued by the Scottish Public Services Ombudsman. This process requires that the complainant is sent the provisional decision or draft report, before a final decision is made on the complaint. This gives an opportunity for issues to be raised if the complainant thinks the Ombudsman body has relied on inaccurate information, or if there is new information that may change the provisional views.
National Health Service (Complaints) Regulations 2021	Regulation 26(1)(b)(ii) - Respondent does not like the word 'chooses' believing that it is totally unacceptable, and it makes the IRB a chocolate fireguard….. again.	This sub-paragraph will be removed.
National Health Service (Complaints) Regulations 2021	Regulation 26(2) - Respondent believes that they should publish the statement on its website.	Agreed that the response should be published by Manx Care. This change will be made in the Regulations.
National Health Service (Complaints) Regulations 2021	Regulation 26(3) - Respondent would like 'and report on same in the annual complaints report' added to the end of this clause.	It is agreed that any decision not to implement the recommendations of the Ombudsman body should be made public.
National Health Service (Complaints) Regulations 2021	Regulation 26(4) - Respondent would like this to say, ' if Manx Care chooses not to follow any recommendation of the IRB, they must submit a report to Tynwald within 14 days of submitting the report to the Department explaining their reasons for choosing not to follow the recommendations of the IRB and outline any potential risk to the public.'	It is agreed that any decision not to implement the recommendations of the Ombudsman body should be justified.
National Health Service (Complaints) Regulations 2021	Regulation 27(2)(c) - Respondent has stated, 'What??!!'	If reviews took more than 6 months to be concluded the Ombudsman body must report on what action it took to ensure that those reviews are concluded within 12 months.
National Health Service (Complaints) Regulations 2021	Regulation 27(1)(e) - The respondent would like this to include the length of time the recommendations have been outstanding.	Agreed, this change will be made.
National Health Service (Complaints) Regulations 2021	Regulation 27(1)(f) - The respondent would like this to include '(whether complaints have been made to the IRB directly, the Tynwald Ombudsman or other third party)'.	Currently the only route would be to make the complaints directly to the Ombudsman body and this is what would be reported on.
National Health Service (Complaints) Regulations 2021	Regulation 27(1)(h) - The respondent would like this to state, ' Details of any third parties used to produce additional advice, medical, legal, accountancy, training etc.'	It is intended that a change will be made to the Regulations to require details of the persons that have provided the external advice to be disclosed in the annual report.

National Health Service (Complaints) Regulations 2021	Regulation 27(1)(i) - Respondent would like this to state, ' The IRB annual report should also include the IRB annual accounts and proposed budget for the following year, Governance statement, proposals for the following year.'	In the interim position, the Ombudsman body will not have its own budget and so will not be required to keep accounts. It is anticipated that the Independent Ombudsman set up under the Reform Bill will have its own budget, provided through the Government's budget setting process, and will be required to prepare and publish its accounts.
National Health Service (Complaints) Regulations 2021	Regulation 27(1)(j) - The respondent would like this to state, ' details of any recommendations that Manx Care has chosen not to follow.'	This information would be made publically available by Manx Care and so would not need to be restated in this annual report.
National Health Service (Complaints) Regulations 2021	Regulation 27(4) - the respondent would like to see this done, within one month of being laid before Tynwald and provided to any person that contact the IRB and requests the report.	Agreed. This change will be made.
National Health Service (Complaints) Regulations 2021	Regulation 28(c) - The respondent would like this to state, 'Any other information that would normally be available under the Freedom of Information Act, GDPR or Government Access to Information code. ' The respondent has stated that this ensures transparency between the Government and Public.	Freedom of Information Act (FOIA) and the Data Protection Act (DPA) are specific Acts that enable exemptions to be applied if required. This would not be the right mechanism to apply such requirements as it would put the detail of those Acts aside. The Ombudsman body would be subject to registration with the ICO and therefore fall under the requirements of the DPA. The Department does not support a change being made to the FOIA to include the Ombudsman body as the majority of information that it holds will be personal information in relation to the complaints that it reviews, which wouldn't be appropriate to be released in the public interest.
National Health Service (Complaints) Regulations 2021	Regulation 28(d) - Respondent would like this to state, ' hold an annual public meeting where members of the public will be invited to speak and meet members of the IRB.'	This suggestion will not be put into statute. However, more transparency is being given to the Ombudsman body in terms of its reporting and ensuing that contact details and procedures are made public.
National Health Service (Complaints) Regulations 2021	Regulation 29(2)(b) - Respondent would like this to be within a period of one month instead of 6 months.	Noted, timescales for transitional arrangements will be reconsidered.
National Health Service (Complaints) Regulations 2021	Regulation 30(2)(b) - Respondent would like this to be within a period of one month instead of 6 months.	Noted, timescales for transitional arrangements will be reconsidered.
National Health Service (Complaints) Regulations 2021	Regulation 31(4) - Respondent would like this to read, 'The complainant may request that the handling of the complaint be moved from the 2004 regulations to the 2020 regulations.'	Once the Regulations are implemented, all active complaints currently in progress will finish their review under the 2004 Regulations. Any complaints received from the date of the new Regulations will be required to adhere to the new complaints process under the 2022 Regulations.

National Health Service (Complaints) Regulations 2021	Explanatory Note - The respondent has expressed, 'You have not stated the historic situation and the fact that it appears the requirement of 33/06 for independent review of the IRB is still being ignored when it is very easy to rectify.'	Noted, the recommendation was that "There should be an opportunity for an appeal to be made and heard by an independent person outside of the Complaints Panel System. The already approved Ombudsman Service should be established as a priority." It is understood that the "approved Ombudsman Service" you refer to is the Tynwald Commissioner for Administration (TCA). TCA oversight of the Ombudsman body has been considered as part of considering the consultation responses; however, it has been decided that this change will not be made. It is standard practice that the decisions of Ombudsman cannot be appealed other than by recourse to a legal challenge such as Judicial Review. In respect of dissatisfaction with the way in which the Ombudsman body has handled a complaint, the Ombudsman body is required to constitute its own 'corporate' complaints process for considering such matters.
National Health Service (Complaints) Regulations 2021	Explanatory Note- The respondent has expressed, ' For both regulations above, include offence/fine clause similar to FSA (but adjusted for Healthcare situation) to include Manx Care, DHSC and the IRB Offences (1) A person who contravenes the requirements of this Regulation is guilty of an offence and liable — (a) on summary conviction to custody for a term not exceeding 12 months or to a fine not exceeding level 5 on the standard scale, or to both; or (b) on conviction on information, to custody not exceeding 2 years or to a fine, or to both. (2) In determining whether a person has complied with any of the requirements of this Regulation, a court may take account of — (a) any relevant supervisory or regulatory guidance given by a competent authority that applies to that person; or (b) in a case where no guidance falling within head (a) applies, any other relevant guidance issued by a body that regulates, or is representative of, any trade, business, profession or employment carried on by that person. (3) In proceedings against a person for an offence under this paragraph, it is a defence for the person to show that it took all reasonable measures to avoid committing the offence. (4) If an offence under this paragraph is committed by a xxxxxx and it is proved that the offence — (a) was committed with the consent or connivance of; or (b) was attributable to neglect on the part of an officer of the body, the officer, as well as the body, is guilty of the offence and liable to the penalty provided for it. (5) If an offence under this paragraph is committed by a partnership that does not have legal personality, or by an association other than a partnership or body corporate, and it is proved	This does not apply to the complaints handling under the Financial Services Authority's Rulebook and would not be appropriate in the health and care context. The intention is not for offences to be created for individuals when applying the complaints regulations but, instead, a framework is being provided to encourage higher standards in complaints handling and promoting a culture of learning where complaints are viewed as a learning opportunity. Openness and transparency are also being encouraged through greater use of reporting to the public and Tynwald. Consequences will be potential reputational damage.

	that the offence — (a) was committed with the consent or connivance of; or (b) was attributable to neglect on the part of, a partner in the partnership or a person concerned in the management or control of the association, the partner or the person concerned, as well as the partnership or association, is guilty of the offence and liable to the penalty provided for it.'	
Membership of the IRB	Wouldn't a nurse and one or two of the others be classes as "health care professionals" as referred to in (4)? And I personally would think that there should always be at least one of the 8 who is a social worker or a social care worker and at least one of the 8 who is a psychologist or who is a professional that works in mental health?	Agreed, the social care professional will be limited to just registered and recently retired social workers.
Reg 23 (4) For the purposes of paragraph (3)(a), consent may be either express or implied.	I believe that consent is normally required to be express under GDPR. However, I also know that there are other lawful reasons to process personal data without consent, so perhaps this is ok?	Agreed that consent should be express (not implied).
Reg 19 of the NHS (Complaints) Regulations	Complaints to services providers can be made orally or in writing. Complaints to the IRB must be made in writing (per 2006 recommendation should be on a standard form); however, in terms of equality should we allow complaints to the IRB to be made orally? Especially as we cannot bring in the additional independent advocacy service provision without a Bill.	Agreed, this change will be made.
Support for people complaining to the IRB	Is legal aid available for supporting people in making representation to the IRB - should it be?	Legal aid is not available for making representations to the Ombudsman body as it is not listed in the Schedule to the Legal Aid Act. It is agreed that the availability of legal aid should be further considered and this will be done as part of the policy development for the Reform Bill.
Process for complaining	face to face meetings with the complainant are a helpful way to communicate (in addition to formal written communications). A resolution meeting should be offered to the complainant after the final response has been sent	Agreed, this change will be made to the Regulations.
Support for complainants	There is a lack of support for complainants after having gone through the process. Therapy or counselling should be offered as standard.	It is intended that a change will be made to the Regulations so that they include a requirement that the formal response letter includes an offer to supply the complainant with details of any services or support which it considers may provide assistance to the complainant, taking into account that person's needs.

complaints made by children	there may be instances where 16 and 17 year olds are estranged from their parents and may wish to ask for a professional's help in making a complaint. A child should be considered to be someone under the age of 16. Ensure it is clear that complaints can be made by children.	A change will be made to the Regulations to ensure that it is clear that complaints can be made by children or by a representative of a child, if the child would prefer.
Statutory record retention period for complaints records	There should be a statutory record retention period for complaints records	A statutory record retention period of 10 years will be included for service providers and the Ombudsman body.

Appendix 4

Complaints Modernisation Part 2 - Consultation Hub Responses

1. What is your Name?

There were 12 responses to this question. One respondent opted to respond anonymously, and one name was left blank.

2. What is your email?

There were 10 responses to this question, 2 did not provide their e-mail addresses.

3. May we publish your response?

There were 12 responses to this question.

Option	Total	Percent
Yes, you can publish my response in full	**4**	33.33%
Yes, you may publish my response anonymously	**7**	58.33%
No, please do not publish my response	**1**	8.325%
Not Answered	**0**	0.0%

4. Which of the following are you responding as:

There were 12 responses to this question.

Option	Total	Percent
Member of the Public	**9**	**75.00%**
Works for a service provider but is responding in a personal capacity	**2**	**16.66%**
Responding on behalf of a service provider (in which case please provide organisation's name)	**0**	**0.0%**
Other	**0**	**0.0%**
Not Answered	**1**	**8.33%**

5. If you are completing the survey on behalf of an Organisation or group, please provide the name of the organisation (or group):

There were 0 responses to this part of the question.

6. Clear statutory duties

6.1 Do you have any views on the statutory duties that would apply to the Department, Manx Care, commissioned service providers or any independent adjudicator? If yes, please provide your views.

There were 5 responses to this question.

You told us:	We Will:
One body to consider complaints about service providers, except for MHRT cases where the appeal is against compulsory detention and treatment	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
There is no point in a single adjudicator. The Tynwald Administrator system has failed now taking more than two years to deal with a simple complaint. The health service ombudsman scheme in the UK is equally failing and lacks sufficient teeth. The way forward for the Isle of Man is a Health Service Independent Review Tribunal set up in the same way and with the same powers as most other Tribunals and operating out of Murray House. It will have to sit most days of the week to cope with the current level of health service complaints. I would suggest that the legally qualified chair could have a dual role as a secondary coroner of inquests where complaints involve a death in hospital or within a nursing home.	
I have two main principals, accountability and public protection, both of which are currently lacking in the current and proposed legislation. The consultation as it stands makes comments that DHSC/Manx Care are going to comply with the PHSO principals but ignore and doesn't publish some of the principals, for instance, financial remedy. PHSO do no tend to order large amounts but it does provide compensation for a member of the public who has been caused distress or harmed by improper practices. This consultation should have been more candid with the public and provided information so the public can make informed decisions. For instance, the Attorney General providing legal advice and Director of Public Health providing medical advice to the "independent" review body should have been disclosed. The Tynwald Ombudsman report quering the actual independent status of the independent review body has not been mentioned. The consultation refers to changes needed in primary legislation but does not detail what needs to be changed bearing in mind some of the changes that were voted for 15 years ago by Tynwald and ignored by DHSC. The new statutory requirements should ensure that the department has to be candid otherwise history will repeat itself. Please bring in accountability.	

To have a consistent and clear complaints policy and procedure	
If it works for uk should work here	

6.2 Do you have any comments on the Department's corporate complaints policy? If yes, please provide your views.

There were 4 responses to this question.

You told us:	We Will:
It is currently completely useless, takes far too long and is insufficiently independent.	Thank you for your comment, we will review the effectiveness of the policy after 12 months of operation.
Too lengthy and detailed to expect any member of the public to read it and probably very few members of staff are going to read it in full either. This needs to be simplified and shortened significantly. A short leaflet, possibly a tri-fold A4 leaflet, should also be produced for use of the public in understanding how to complain to the DHSC about their interactions with them and/or about strategic direction for health and social care not providing equal opportunities or services that individuals need for example.	Thank you for your comment, we will review the effectiveness of the policy after 12 months of operation.
It is far to easy for MHK members to contact Manx care on behalf of an individual when they should go through the health minister	Thank you for your comment.

6.3 Do you have any views on the role of the Mental Health Commission? If yes, please provide your views:

There were 5 responses to this question.

You told us:	We Will:
MHC should be limited to policy and capacity and be active in between CQC.	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
This could be fulfilled by a revised Mental Health Tribunal	
I know too little about the Mental Health Commission and about mental health to comment here.	
The most vulnerable should always have protections in place to ensure that they can complain and be supported to do so.	
.? Still relevant to be separate, can't it be within health services.	

7. Complaints standards for private health and social care services

a. What comments do you have about complaints handling by private health and social care service providers?

There were 6 responses to this question.

You told us:	We Will:
They, private service providers, should have service provision standards, local resolution (it's hard to deal with a UK body) and complaint investigation, There should be the right to review by IRB if dissatisfied. This is about safeguarding rights of patients.	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
There should be a unified system with supporting legislation	
Only services that are mandated by DHSC to Manx Care should be regulated to the extent discussed above. There are private individuals and organisations that provide services that are already regulated and inspected by RIU but the services they provide are nothing relating to what is contained in the mandate to Manx Care i.e. childminders and nurseries. By extension, there are also private individuals and organisations that provide alternative remedies and treatments which cover a wide range of services including acupuncture, sports massage, essential oils and herbal medicines. It would be impractical to regulate these types of services. For starters, how would you define in the legislation whether a remedy or treatment provided by a private individual or organisation is one that would require registration and regulation by the DHSC? Is it even right that these services should be regulated by one central authority? Many of these services are practiced with an element of personal belief because the science is not proven. Individuals have rights to freedom of personal belief that could be impacted by being seen to oversee areas where science has been unable as yet to conclude one way or the other regarding efficacy of treatments and remedies offered by such practitioners.	
there should be a legal requirement for all services to have a complaints policy and procedure and all services should be registered and regulated	
Should cover all providers	

7.2 Do you think the Department should have a role in relation to setting standards for complaints handling by private health and social care service?

There were 8 responses to this question.

You told us:	We Will:

As above, a unified code of practice for complaints handling is required	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
Only mandated services should be overseen by the DHSC.	
The Department should be satisfied that such procedures are in place, rather than directly involved in setting them.	
yes the government should take some responsibility in the registration of these groups and have a duty and responsibility for public welfare and be able to investigate accordingly	
they should set the base line standard which providers should not fall below but can exceed	
It needs to be a standardised process.	
Should all offer standard healthcare	

7.3 Do you think the Department should have a role in relation to setting standards for complaints handling by private health and social care service?

There were 4 responses to this question.

You told us:	We Will:
yes the government should take some responsibility in the registration of these groups and have a duty and responsibility for public welfare and be able to investigate accordingly	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
they should set the base line standard which providers should not fall below but can exceed	
It needs to be a standardised process.	
Should all offer standard healthcare	

8. Options for an independent adjudicator

8.1 Do you have any views on which of the above options for an independent adjudicator would be most preferable?

There were 4 responses to this question.

You told us:	We Will:
Yes. Existing combined IRB to be renamed Health & Care Ombudsman Service. This to be local.	The Department considered the responses when determining how to progress with the Ombudsman body that is being proposed in the updated draft Regulations. Further changes to increase the independence of the Ombudsman will be considered as part of the policy for the Reform Bill where it is proposed that enhancements will be made. These comments, along with any learning that can be taken from the interim arrangements, will be taken into account when developing the policy for the future Ombudsman.
As previously stated. This should take the form of a Tribunal with a legally qualified chair. and a right of appeal. The other options won't properly cope with the demand, will produce poor outcomes for complainants and take far too long.	
I do not believe that a combined IRB is the best that the Island can offer for independent adjudication of complaints about health and social care services. Neither do I believe that the Tynwald Commissioner is at all suitable for reviewing such complaints - she lacks the expertise to understand the nature of the complaints.	

I believe a stand-alone ombudsman would be provide for a truly independent adjudicator and also provide the necessary expertise required. I would question whether the existence of contract would limit the independence of an independent adjudicator, so would favour contracting with an appropriate external party through the UK Ombudsman Association nor contracting with off Island professional external investigators. Whilst a stand-alone ombudsman would still require funding from somewhere and would be dependent on that, the funding could be provided directly under the legislation that forms the ombudsman and this would be better than funding coming from the DHSC who might be able to withhold funding or attach conditions to the provision of funding.	The Department will re-consult on its proposals in due course.
The newly-combined IRB makes sense.	
an independent Ombudsman	
Make use of the uk or off island expertise.	

8.2 Should the independent adjudicator's remit include complaints relating to health and social care services that are funded privately?

There were 6 responses to this question.

You told us:	We Will:
This is to protect and safeguard service users. How the service is funded is irrelevant	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
But only so far as would reflect what is done in the UK. If a private health or social care service is not subject to complaints review by an ombudsman in the UK then they should not be subject to publicly funded independent adjudication in the IOM.	
It should cover all health and social care to ensure that no-one can fall through gaps.	
sometimes we need independent reviews regardless if they are public or private	
to ensure all providers are held accountable for the services they provide and that complaints are dealt with appropriately	
Individuals choice to go to a private clinic, they should follow their principles.	

8.3 Should the independent adjudicator's remit include complaints relating to the detention of a person under the Mental Health Act 1998?

There were 6 responses to this question.

You told us:	We Will:
It's a very different thing.	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
The remit could include this and I could see a Tribunal being able to resolve this type of issue very quickly as they do at present.	
I do not know enough about mental health to have a view on this.	
I believe that with a common adjudicator in all areas the potential for errors and misunderstandings will be lessened	
the Island is of a size where one service should be able to cover all Health and Social Care services	
Mental health should be part of health services	

8.4 What areas of concern should the independent adjudicator look at when carrying out a review into a complaint?

There were 5 responses to this question.

You told us:	We Will:
1. Did the matter involve a death 2. Did the matter involve serious risk to health and risk to the wider general public 3. Is there a health professional that needs to be urgently removed/retrained/reprimanded 4. Is there a party that should be compensated 5. Is management at fault 6. Do procedures need to be changed 7. What steps should be taken to improve matters for the future	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
Transparency about the incident. Professionalism and basic customer service standards. Harm or risk of harm. Equal opportunities and reasonable accommodations that should be made for service users.	
All relevant information, which could be very wide.	
Has the complaint be managed appropriately	
Make sure all opinions from parties are treated fairly	

8.5 Should the independent adjudicator be made up of (a) lay members, (b) professionals that are experienced in health or social care, (c) professionals experienced in complaints handling and dispute resolution or (d) a mixture of these options?

This was a closed question; 12 responses were received.

You told us:	We Will:
• 10 respondents selected (d) a mixture • 1 respondent selected (a) professionals that are experienced in health or social care	The Department considered these responses as part of developing its proposals for the Ombudsman body under the Regulations. It has determined that the members should be a mixture of health and social care professionals

• 1 respondent selected (b) and (c) professionals that are experienced in health or social care and professionals experienced in complaints handling and dispute resolution.	(or recently retired professionals), professionals experienced in complaints handling and dispute resolution and a chairperson with legal expertise will be required.

8.6 Who should appoint the members to the independent adjudicator to ensure independence?

This was a closed question; 8 responses were received.

You told us:	We Will:
2 responses suggested the Appointments Commission 2 responses suggested a suitably qualified independent third party 2 responses suggested Tynwald 1 response was a UK Body 1 response suggested the body should appoint its own members	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022. Under the Regulations the Appointments Commission will appoint members of the Ombudsman body.

8.7 Where and how should the independent adjudicator be required to report?

There were 5 responses received to this question.

You told us:	We Will:
Complainant, service provider, Manx Care, DHSC and if appropriate MHC and professional/regulatory bodies	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022. Under the Regulations the Ombudsman body is required to report to Tynwald through the Department.
Directly to Tynwald and be prepared to take and answer questions	
The independent adjudicator should report on individual cases publically within one month of resolving same. The report should be laid before Tynwald and published on a website. Normal redaction of personal information will apply. There should also be an annual report filed within three months of the financial year end, normally 31st March. So the annual report should be laid before Tynwald by 30th June and made publicly available online at the same time. The independent adjudicator should not provide reports to DHSC, Manx Care or anyone else beforehand. The report is the report and should not be open for discussion or amendment by DHSC, Manx Care or any other Government Department. The report should include the number of cases, time taken to resolve cases, any patterns of issues, budget, accounts, staffing,	

future plans, Governance arrangements etc. A public meeting should be held each year.	
Tynwald	
Manx Care	

8.8 Should the independent adjudicator be allowed to launch its own investigations on issues of concern without first having to have had a large number of complaints?

This was a closed question; 10 responses were received.

Option	Total
Yes	**8**
No	**2**

If yes:-

You told us:	We Will:
There should be an investigative capacity from a pool of retired police officers/retired and non practising advocates/solicitors	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
This would again increase their independence. Ombudsman organisations in the UK do this.	
They should have the power to act if they see it as necessary.	
Depends on nature of complaint	
Some areas may only have small numbers, but local knowledge may alert to an issue.	

9. Who should be able to make a complaint

Do you think it is a good idea to have a mechanism to allow people that have been made aware of issues but have not been directly impacted to raise issues?

This was a closed question; 10 responses were received.

Option	Total
Yes	**7**
No	**3**

If yes:-

You told us:	We Will:
But limited to: Magistrates (from Child Care Cases) High Bailiff (Mental Health and Drink & Drugs cases) Coroner (Deaths) Tribunal Chairs (Health related cases)	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
MHKs can already do this via Tynwald questions. In fact, they are now able to submit written questions any day of the year and the answers will be accessible to the public online. MHKs do not	

require any additional specific mechanism to raise issues they are aware of. Coroners and Tribunal chairs might benefit from such a mechanism as the reports they currently publish relate to a single incident/case matter. Such a mechanism might allow them to highlight patterns they have found that cover multiple cases/incidents.	
yes think that this is critically important to avoid the suppression of information by individuals within an organisation under potential investigation	
Yes. All of the above mentioned should have the right to make a complaint as well as others, for instance Charities that are seeing issues. The Hospice might also have input because they may be hearing stories repeatedly from their patients. There should be a statutory requirement to effectively whistleblow. Once a person has raised an issue the liability should then pass to the complaints procedure and failure to act should have accountability.	
It is in the public interest	

10. Access to records and data sharing

10.1 Should the ability for individuals to access records of a deceased person be extended to include social care records as well as health records?

This was a closed question; 12 responses were received.

Option	Total
Yes	**11**
No	**1**

10.2 What limitations should there be, if any, to the ability for individuals to access health or social care records of a deceased person?

There were 9 responses received to this question.

You told us:	We Will:
There must be a properly appointed estate representative	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
They should have to be a direct blood relative	
The requestor should be someone who has a good claim to be acting on behalf of the deceased in making a complaint or to be someone significantly affected by alleged poor treatment of the deceased.	
There should be good reason to do so.	

10.3 Do you think additional guidance in relation to data sharing is needed for complainants?

This was a closed question; 12 responses were received, however there were some additional comments provided as explanation for the answers.

Option	Total
Yes	**11**
No	**1**

If yes:

You told us:	We Will Do:
At present it's hit and miss. Service providers need to be able to identify what is a complaint, how to investigate and to resolve issues with complainant. They need to record and evidence the evidence and investigations and record the outcome and recommendations	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
Quality standards should be drafted by a person qualified in quality standards. These standards should be inspected and regulated by the CQC. At the moment the CQC will only have the power to inspect, not regulate. This is not acceptable. Too many reports have been issued previously and DHSC failed to take action. Standards need to be issued and audited.	
This is required for uniformity	
it would be the best practice to ensure other providers have guidance	
It will encourage consistency in responses.	
Just manxify the English version for reference purposes	

11. Do you have any other feedback on areas that the Department should consider in relation to the arrangements for health and social care complaints?

There were 5 responses received to this question.

DHSC Response:

You told us:	We Will Do:
The entire system should have been replaced years ago and the current proposals are only following the UK. The UK is little better than the Isle of Man. I would be happy to meet and discuss how improvements could be made.	Thank you for your feedback. The responses received will be considered in detail as part of the policy development for the Reform Bill. The Department commits to providing an update on progress with development of this Bill by the end of 2022.
the greatest area that needs addressing is in relation to Family Carers, an area identified in the Michaels report as urgently in need of attention. I believe that legislation needs to be introduced to establish family care as a profession and that Government need to then establish a wage level	

for family carers commensurate with their ability. This would both dramatically reduce the number of complaints in regard to provision made for family carers and their charges as well as significantly reducing government spending on their in house provision as well as providing an enhanced standard of care for family members who can be accommodated within their family environment	
You have failed to advise why it appears that despite a vote of Tynwald in 2006 instucting DHSC to ensure health complaints were subject to an independent ombudsman, there is an effort to delay again without explanation rather than some muttering about primary legislation issues. This is wholly unacceptable, the wishes of Tynwald were clear 15 + years ago and this needs to be resolve immediately even if it is a stop gap, for instance, the Tynwald Ombudsman having jurisdiction to investigate Manx Care and the IRB for maladminisration. In April 2021 Tynwald asked that you bring these regulations forward in November 2021 and I expected to see some sort of Ombudsman to protect the public. The number of complaints are not high but the stakes are - public harm or death. The IRB have been totally silent on this issue. The DHSC / IRB complaint reports for 2020/21 should have been laid before Tynwald circa September 2021 and have not been produced so the public do not have up to date information albeit the number of complaints will be lower due to the covid pandemic. The public expect you to carry out the wishes of their elected representatives and therefore expect to see a Ombudsman facility when the regulations are laid before Tynwald next month.	
It is always our concern that the most vulnerable have accessible avenues for them to complain. This includes the homeless, the illiterate [sic], those with limited communication skills and education, and those with other social difficulties. These people require a patience, flexible, kind and helpful hand to enable them to complain if they wish to do so.	
Cover all providers of health and social care. Recent issues with COVID has meant some healthcare providers are left in limbo such as dentists, chiropodist, pharmacists	

Appendix 5

Pre-Consultation Responses

Topic	Issue/Feedback/Query from consultation	DHSC response
Alternative suggestions for investigating/ reviewing complaints	"an expert external review may be offered… In [*redacted*] view, a reliable, off Island professional group of investigators specializing in DHSC complaints (such as [*redacted*]) could be commissioned to look at all unresolved serious complaints. [*redacted*] would have access to reliable experts and be truly independent. [*redacted*] would be familiar with the complex nature of some complaints and, although probably expensive, would make sensible recommendations for improvement at an early stage."	This will be considered as a longer term policy option for the independent adjudicator.
Alternative suggestions for investigating/ reviewing complaints	"The complaints procedures should align with and connect into professional standards and [professional] bodies. The role of these bodies and references to them should be understood by staff and patients alike."	Professional bodies' standards are generally set out in Codes of Conduct, which derive their authority from the statutory basis of most professional regulatory bodies. There is an argument for the Regulations to include provision that referral to a professional 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.
Alternative suggestions for investigating/ reviewing complaints	"The role of whistle-blowers is not considered anywhere apart from in the motion."	There is a new Government wide whistleblowing policy being created and due to be consulted upon which will apply consistent standards across Government. Clarity needs to be given to staff on what should be treated a whistleblowing and what should be treated as a complaint as they are 2 separate processes. Whistleblowing is when anyone who provides a health or social care service raises a concern after witnessing an event. They may have no direct personal involvement in the issue they are raising but want to speak up in the public interest where an act or omission creates a risk of harm or wrongdoing. These issues are classed as protected disclosures under the Employment Act 2006 and, when reported, should follow

		the whistleblowing policy and process. It is important to identify where a non-whistleblowing issue is raised by someone who provides services but the issue is raised in the capacity of a service user (i.e. where a staff member is receiving services and has cause to compliant about their experience). This should be handled as a complaint under the complaints policy and procedures. Where an issue raised in a complaint overlaps with issues raised under the whistleblowing process, the complaint should still be responded to as a complaint.
Alternative suggestions for investigating/ reviewing complaints	"Should be 3 stage, local resolution, IRB, Ombudsman."	This suggestion does not align with best practice standards endorsed by the Ombudsman Association. A simple two stage process will be implemented for handling complaints. The Tynwald Commissioner for Administration could have a role in reviewing complaints about maladministration by the IRB as this is a current gap. This will be discussed with the Tynwald Commissioner for Administration and consulted upon.
Alternative suggestions for investigating/ reviewing complaints	"Actually there are 4 options not 3 - Ombudsman should be contracted from UK ombudsman assn so entirely independent. Private included-Yes Review whether processes correctly followed and verdict correct. Should be ombudsman trained with legal and medical experience. Reports to holder of complaint -DHSC or Manx care who share it with Minister/Tynwald Gov contract to external provider for a binding decision on process and verdict."	This suggestion will be considered as part of longer term policy options for an independent adjudicator.

An independent adjudicator or ombudsman to replace the IRB	"[*redacted*] see no reason why the IRBs and other issues cannot be restructured in time for November 2021… If the complaint regulations and the IRB situation is not resolved by November 2021 then [*redacted*] advice to future complainants would be to bypass the DHSC/Manx Care complaints system and refer the complaint directly to the professional body… there should be no delay in appointing an Ombudsman and this should be done by November 2021 even if using the Tynwald Ombudsman for this service is an interim measure. A check on maladministration will improve the system immediately." "[DHSC] have inserted themselves into the complaints procedure issued in April 2021 which is a conflict of interest"	The current vires will allow a joint ombudsman to be formed with statutory timescales for responses and a process for reviewing complaints set out in legislation. It is also the intention to amend the legislation to allow the Tynwald Commissioner to have a role in reviewing complaints in relation to maladministration of the IRB's handling of complaints. This would provide a mechanism by which complainants who experience maladministration causing injustice on the part of the IRB can refer their concerns to a truly independent arbiter. This would focus principally on the way the IRB has conducted itself in procedural terms, not the substance of the complaint referred to the IRB (e.g. a care and treatment matter etc.). Limited jurisdiction by the Tynwald Commissioner would retain the IRB's integrity where its core function is concerned (the 'independent' consideration of health and care complaints) but provide for administrative justice on the more narrow point of whether the IRB has conducted itself in line with its statutory remit and responsibilities. This will be an interim measure on the journey towards a process that more closely reflects statutory arrangements and best practice across the UK nations and internationally. It is agreed that not all issues may be for service providers to resolve. In cases where an individual is unsatisfied with standards of conduct, ethics or performance by an individual health professional, it may be for the respective professional body to investigate. These include, for example the Nursing and Midwifery Council, the General Medical Council, the General Dental Council, the Royal Pharmaceutical Society, and the General Optical Society. Where serious concerns about a registered healthcare worker are identified, a

		referral to the appropriate professional regulator could be made by the complainant and should be made by the service provider to whom the issue was reported. The DHSC's role in the complaints will be reset as part of this review of legislation. The Department should not be an active player in the complaints process in relation to services (as with the DHSC's role in England). It is not a provider of services and the complaints procedure should only apply Manx Care and its commissioned agents.
An independent adjudicator or ombudsman to replace the IRB	"The Governor [of the IRB] had not read or considered the complaint file properly. Offers to meet repeatedly were denied, the Governor quoting process. Access issues were not considered by the IRB, their demands quoting internal procedure were impossible to navigate. Demands that a bereaved complainant review a [*redacted*] medical records for a third time (which include colour scans of [*redacted*] internal organs) is not acceptable on any level but forms the basis as to why my particular complaint was refused… complainants do not have a right to attend staff panel hearings. In [*redacted*] case it didn't get that far but complainants should have that right, perhaps with the options of submitting questions to staff via the Governor/Panel…	The IRB procedure will be given more transparency by being set out in the Regulations and a statutory requirement for effective publicity to be given to its procedures will also be included.

An independent adjudicator or ombudsman to replace the IRB	Please see below list of things that the [Parliamentary and Health Services Ombudsman] provide which the IRB do not. Public website Public telephone number Public helpline Willingness to discuss queries over the phone Social media presence (twitter, Facebook, newsfeed etc.) Annual public reports (currently only to DHSC) Annual public Accounts (currently only to DHSC) Annual public open meeting Public consultations on their service Internal complaints procedure on their service (IRB have none) Public statement on their principles Freedom of information requests (IRB currently claim exemption) Data protection statements Ability to investigate public hardship or injustice (IRB do not. They are silent on maladministration) Leaflet provided at end of service provider process (DHSC advise contact IRB but provide no address etc.) Internal medical advice (IRB use the director of public health).” Feedback welcomed on their service (IRB ignore any critical feedback) User friendly and modern documentation setting our your rights (IRB format has been the same for years and omits certain rights) Disability /Equality statement Control over who is employed by them (Comin appoint the IRB, the IRB have no control) Staff holding relevant qualifications Internal legal advice (IRB use AG office)	There will be a requirement for the joint IRB to give effective publicity to complaints arrangements within the Regulations, which would cover having a webpage and telephone number. Other requirements in the regulations will cover a public reports to Tynwald, contact details for the IRB to be provided by the service provider at the end of the local resolution process, more professionals and qualified members of the IRB to cover the requirement for medical advice. Whilst we agree in principle with this comment, some of the information is best practice operational suggestions. The joint IRB will be encouraged to apply best practice advocated by the UK's Ombudsman Association to its operation. In the longer term, the aim is to move towards a set up that is more similar to the PHSO but on a smaller scale and appropriate for the Isle of Man context.

An independent adjudicator or ombudsman to replace the IRB	"The IRB are not qualified and do not deal with maladministration, public injustice etc. This is the role of the Tynwald Ombudsman. The IRB are also not qualified to deal with issues on Candour. The ability of the Ombudsman to review was clearly stated in 33/06… An Ombudsman should be appropriately qualified with ombudsman qualifications"	It is agreed that the IRB are not currently qualified as they are lay members. It is intended that the revised, joint IRB will be set up differently with more qualified professionals as members. There is a duty of candour procedure set out in Regulations for service providers to follow. Any duty of candour incidents that result in complaints would be reviewed as complaints. Any that are not resolved at local resolution stage will be within the remit of the revised IRB. Training for IRB members will be required and could cover the duty of candour procedure. The Ombudsman requirements in 33/06 require an opportunity for an appeal to be made following an IRB review that would be heard by an independent person outside of the Complaints Panel System. This does not align with the best practice standards endorsed by the Ombudsman Association. The best practice position is that there should be one independent adjudicator. The ability of the Ombudsman (in this case the Tynwald Commissioner for Administration) to reopen and reconsider the complaint after the IRB review would result in the ability to overturn the independent adjudicator's decision. This would have a number of quite serious implications for the process and undermines the principle that the independent adjudicator is the final neutral port of call in such a dispute. However, the ability for the Ombudsman to review complaints about maladministration by the IRB could be included as part of a review of the legislation and will be consulted upon.

An independent adjudicator or ombudsman to replace the IRB	"IRB annual reports should be every year… Any independent adjudicator should report annually and publicly. The independent adjudicator should be appointed by Tynwald… Any independent adjudicator should have similar powers of enforcement to that of the CQC."	Annual reports from the IRB to Tynwald are proposed within the Regulations. The comments made in relation to the appointment of the independent adjudicator and its powers will be considered for the longer term independent adjudication solution. However, it should be noted that there is a fundamental difference between ombudsmen/independent adjudicators and regulators (such as CQC). CQC's powers have mandatory force and non-compliance can result in legally enforced sanctions. Ombudsmen however can only make 'discretionary recommendations', and this is an established principle accepted by the Ombudsman Association. Nonetheless, in instances where an organisation resists such a recommendation, the matters can reported to a responsible body (such as Tynwald) for consideration, or alternatively pursued through the judicial system. Giving an independent adjudicator or ombudsman a mandatory power of enforcement could result in legal challenges (e.g. private contractors operating commercially on an independent basis under a commissioned arrangement to Manx Care).
An independent adjudicator or ombudsman to replace the IRB	In relation to the IRB; "[*redacted*] cannot recall the appointment process, but again there should be input from the appointments commission rather than appointment by the Department."	It will be suggested that the appointments commission appoints the joint IRB.
An independent adjudicator or ombudsman to replace the IRB	"The jurisdiction of the [Tynwald Commissioner for Administration] over the adequacy of the process can be dealt with expeditiously."	It is agreed that the Tynwald Commissioner for Administration could have jurisdiction over complaints about the IRB, as otherwise patients and service users would have no recourse to remedy & redress where the IRB is responsible for maladministration causing injustice. This will be discussed with the Tynwald Commissioner for Administration and consulted upon.

An independent adjudicator or ombudsman to replace the IRB	The IRB system is truly independent and its retention is a serious option which should be included in the long term policy options. The Island has a track record of producing highly cost effective solutions - The Financial Services Ombudsman Scheme is a good example. It is remarkably similar to the IRB system	Agreed that this should be included as an option within the longer term policy options for independent adjudication.
An independent adjudicator or ombudsman to replace the IRB	"Combining the IRBs is the way forward but there has to be a change in their title and how they are set up and appointed to"	Agreed this will be covered in the Regulations.
An independent adjudicator or ombudsman to replace the IRB	The inclusion of all health care providers including private would be welcomed.	Noted and will be considered alongside the responses to public consultation.
An independent adjudicator or ombudsman to replace the IRB	"[*Redacted*] strongly supports the option of having a stand-alone ombudsman as a separate legal entity. Whether recruitment should be on Island or via the UK Ombudsman's Association is a matter for debate when weighing accessibility and cost against independence. We would not support the options of extending the remit of the Tynwald Commissioner or of the DHSC assuming responsibility for this role in a regulatory capacity."	Noted and will be considered alongside the responses to public consultation.
An independent adjudicator or ombudsman to replace the IRB	"[*redacted*] is in favour, in the longer term, of an Independent Ombudsman, independent from the DHSC, that reports direct to Tynwald and that such a body should cover both Departmental services and Private services."	Noted
An independent adjudicator or ombudsman to replace the IRB	"the IRB is unfit for purpose. Complainants are unhappy as: they perceive it as biased because the convenors are government paid. it's slow it can only make recommendations there is no feedback loop to check these are adopted there is no ongoing audit of prior recommendations there is no appeal For defendants the process is akin to a 'kangaroo court' where staff are summoned to appear with no 'friend' or union rep allowed to accompany them for support."	This feedback will be considered for the review of the IRB's process in Regulation. The joint IRB will continue to be paid by the Government in this interim stage. Timescales will be included within the Regulations to address slow responses. Recommendations and a feedback loop with the DHSC ensuring that changes are implemented was brought in under the April 2021 Regulations and will be retained and strengthened by also being included within annual reporting to Tynwald. It is considered correct that there is no appeal against the IRB as the independent adjudicator; however, there should be a mechanism to raise complaints about the IRB's process in reviewing complaints, which is planned to be via an

		internal complaints procedure in relation to the IRB with escalation to the Tynwald Commissioner for Administration. The suggestion for staff members to be accompanied will be considered for inclusion within the Regulations.
An independent adjudicator or ombudsman to replace the IRB	"As [*redacted*] Have indicated, [*redacted*] should like to discuss with you the question of the possible involvement of the Ombudsman's Association."	Agreed
An independent adjudicator or ombudsman to replace the IRB	In relation to the Department reviewing complaints as an option instead; "for "lack of perceived independence" [*redacted*] should be grateful if you would substitute "perceived lack of independence"."	Agreed
An independent adjudicator or ombudsman to replace the IRB	"If the long term policy is to move to an Ombudsman scheme, will the combined IRB be seen as an interim measure, and if so for how long?"	Until the NHSCS Bill is completed, current estimation is approximately 3 years. However, the Transformation Programme is seeking additional resource with the aim to reduce this timescale.
An independent adjudicator or ombudsman to replace the IRB	"The Ombudsman scheme will presumably require 'full time employees'? Including Contracts of Employment which are outside the remit of the [*redacted*]. However, there may be some advantage in employing the [*redacted*] experience to identify and recommend."	Agree for longer term policy on independent adjudicator.
Complaint made to the service provider	"The IOM should align their process to the UK, i.e. if a concern is not dealt with in 1 day, it is logged as a complaint."	The approach adopted in the UK has merit. In instances where a concern is raised by a patient/service user and action is taken within one day to resolve the matter, it is not regarded as a 'complaint'. This may act as an incentive to deliver an immediate remedy. It is proposed to include this within the Regulations.
Complaint made to service provider	"What details?" In relation to when the acknowledgement is sent to the complainant.	The detail will be set out within the Regulations. It is proposed to include: (i) a summary of the complaint; (ii) where a complaint was made orally, be accompanied by the written record of the complaint with an invitation to the complainant to sign and return it; (iii) details of the service provider's complaints handling procedures; (iii) inform the complainant how long they can expect to wait to receive a further response; and (iv) give the complainant contact details for an individual member of staff acting on behalf of the service

		provider; (v) if appropriate, request clarification or further details in writing.
Complaint made to service provider	About Manx Care being required to set up a PALS and an advocacy service and to consult with the public; "Timescales need to be inserted for these actions"	Timescales will be set as part of transitional arrangements within the Regulations.
Complaint made to service provider	The 2 working day timescale for acknowledging a complaint is a laudable aim but is it really practical in a 24/7/365 organisation?	It is proposed to change the timescale for acknowledging a complaint to 5 days to be aligned to the process in England.
Complaint made to service provider	"Can a Mental Health Tribunal Chair raise a complaint?... Can a coroner raise a complaint?"	Only a person affected by a issue, or a person acting on that person's behalf, can raise a complaint. This is in line with best practice guidance for complaints handling.
Complaint made to service provider	"The process of nominating someone to assist or deal with a complaint on someone's behalf needs consideration… What happens to someone who has a complaint and retains powers of attorney?... Roles of MHKs in the complaints process. Manx Care approach of ensuing all political contact goes through the CEO seems a poor use of a CEOs time. The public should not be deterred from approaching MHK's."	A complaint can be made by a person affected or their representative if the person has died, is a child, does not have capacity or has requested the representative to act on their behalf. There is also the proposal to include an independent advocacy service which would allow people to use an independent person to assist complainants. How this principle of advocacy is administered in practical terms is an operational matter.
Complaints regulation for commissioned service providers of health and social care	"Complaints procedure should be in contracts with overseas service providers/organisations, it is understood some are delaying the process"	It is intended that the Regulations being consulted upon will require all service providers that provide services under the mandate to have complaints procedures and arrangements for handling complaints in place that are compliant with the provisions of the Regulations, unless there is equivalent legislation in place (for example, in England). There will also be a requirement in the mandate for Manx Care to ensure that there is a complaints procedure for all commissioned providers. This should then flow through to the contracts with those providers. This would apply to any new contract that Manx Care puts in place with providers from the date that the Regulations come into operation.

Complaints regulation for commissioned service providers of health and social care	"On point (e) in page 5, [*redacted*] think that the matters you mention can be dealt with either by specific terms in the contract under which the external provider is engaged or a looser arrangement such as a service level agreement. No doubt the civil team in the AG's Chambers will have a view on the best way to address it."	Agreed
Consequences for breach	"The consequences for breach must come in by November 2021. There is no point in drafting regulations which have no consequences."	The Department will be held to account through its annual reporting to Tynwald, parliamentary committees and the Tynwald Auditor General (once appointed). Inspections of service providers will be carried out by the external inspectors appointed under the Manx Care Act 2021, which may highlight failings in the area of complaints handling. Such reports will be made public along with Manx Care's action plan for addressing the short comings. The Department will hold Manx Care to account in implementing the action plan. Manx Care will also be held to account via its annual reporting to the Department in relation to complaints. The draft Regulations require Manx Care to provide such an annual report within 3 months after the end of the financial year. Ombudsmen (in this case the IRB) can only make 'discretionary recommendations', and this is an established principle accepted by the Ombudsman Association. Nonetheless, in instances where an organisation resists such a recommendation, the matters can be reported to a responsible body (such as Tynwald) for consideration, or alternatively pursued through the judicial system. Giving an independent adjudicator or ombudsman a mandatory power of enforcement could result in legal challenges (e.g. private contractors operating commercially on an independent basis under a commissioned arrangement to Manx Care). The annual reporting requirement for Manx Care will include that any complaints where recommendations of the IRB were

		not acted upon must be identified within the report and the reasons must be given as to why they were not acted upon. It is also suggested that the IRB should report to Tynwald on an annual basis and that that report should detail progress against all accepted recommendations that remain outstanding. The Department has the power under the Manx Care Act 2021 to direct Manx Care and ultimately to remove Board members.
Formal response to the complainant	In relation to any remedial action required by the service provider; ""Prompt" is not sufficient, there should be a timescale".	The actions required under this section could be so variable that it is not considered useful to include a timescale for this action to be taken. However, it is proposed that the response to the complainant will be required to set out the actions to be taken and a reasonable timescale for completion of those actions.
Formal response to the complainant	"Patients should be made to feel their complaint has been valued and not a tick box exercise. Feedback should be provided on how their input has ensured similar events do not happen again. In addition, at the end of the process standardised feedback forms should be sent to the complainant asking how useful they felt the complaint process had been. These feedback forms should be included in the annual report and will highlight if the system is working"	Broader wording will be included which requires service providers to ensure that appropriate mechanisms are in place for complainants to share feedback about their experience of the complaint handling process.
Formal response to the complainant	"A commitment to jargon free language would also be a really useful commitment at this early stage. It would also be helpful if response letters contained balanced information, i.e. the facts that support the complaint as well as the contrary evidence. This is an acknowledgement that their points have been considered and listened to. Response letters must deal with all of the issues raised by the complainant."	It is agreed that this is all important in relation to complaints handling. It will be part of the behaviour and systemic change in culture that will be encouraged through advocacy for the adoption of best practice standards.
General	In relation to the NHSCS Bill; "timescales need to be accelerated"	The Transformation Programme is looking to recruit additional resource to be able to accelerate the timescales.
General	In relation to inspections; "it only identifies CQC as carrying out inspections – [*redacted*] understanding is that there will be a number of regulators working across Manx care services and other providers should the wording not reflect this."	Agreed - wording changed in policy proposals document and will be reflected similarly in the consultation paper.

General	"some of the statutory responsibilities could be laid out in the regulations and not primary legislation."	Acts of Parliament and Regulations are all statutory in nature. The former are primary legislation, and the latter are secondary legislation. Regulations flow from a preceding Act, and are given force by the relevant Act. The responsibilities for complaints handling in relation to services and the IRB's responsibilities can be set out in Regulations and so will be statutory responsibilities. The DHSC's responsibilities in relation to complaints can not be set out in statute as the current Acts only refer to functions in relation to services.
General	"Complainants may be timed out of complaints to GMC etc. because of the length of time it has taken Manx Care/DHSC and the IRB to deal with the complaint."	Referrals to professional regulatory bodies by the public is a separate matter not directly related to the operation of the NHS complaints process. However, this could be covered by guidance issued by the DHSC to make the public aware of all avenues in relation to pursuing a complaint. In relation to the specific example given it is noted that the GMC website states that "There is no time limit for raising a concern."
General	"Access to Health Records and Reports Act 1993. At the moment the Information Commissioner is unable to assist with complaints regarding the aforementioned. This Act is used by the bereaved to obtain medical records for the deceased. This leaves the bereaved in a position of seeking legal advice which is not acceptable. This situation needs to be addressed by November 2021."	Changes to the Access to Health Records and Reports Act 1993 is not within the scope of the review of Complaints Regulations but will be looked at in a future review of primary legislation. Consideration has been given to the joint IRB having the correct data sharing permission to be able to access the records necessary to complete a review of the complaint.
General	"as a KPI of the process is the length of time it takes for the hospital to release records. Complainant should not be required to make their complaint without being able to consider the medical evidence." "How does technology development comes into it? Especially direct access to medical records." "Records of complaints. Amendments to patient records. Destruction of complaint records."	There are processes through which complainants can access medical records; however, these may not always been fully understood. The additional advice function suggested for the DHSC and the introduction of a PALS service should help the complainant to navigate the processes more easily. The extended time frame for making a complaint should also ensure that the length of time it takes for the hospital to release records does not prohibit complainants from making a complaint. Consideration has also

		been given to ensuring that the joint IRB will have the necessary access to records to be able to conduct a review of the complaint and it is the intention to include a standard response time for records to be released.
General	"Funding for legal assistance where required, including legal aid." "When can Manx Care / DHSC appoint legal advice and how then can / does the complainant respond."	This is not a matter for procedural reform.
General	Tacit acceptance that complaints are not being appropriately handled and learning not taking place is implied by the suggested actions to address this. [Redacted] are concerned that, although progress has already been made, the required changes are still urgent and must continue to be made alongside this consultation process, regulation changes and ultimately new legislation. [Redacted] suggest that the Introduction could reference Duty of Candour within the Manx Care Act, since this process and its consequences are a good example of the outworking of these principles (be seen to deliver).	Agreed that current complaints handling will continued to be looked at through the assurance process and through advocacy for the adoption of recognised best practice standards.
General	Comment that recommendation 4c is unclear which states "c) include a role for the Department's in offering advice and guidance on how to progress complaints for health and social care services complaints across the whole national health and social care system in the arrangements set out within the revised complaints Regulations";	Noted and will be clarified for the consultation paper.
General	"[Redacted] strongly agree with Rec 6 but request clarity on who would decide what is adequate, and how; and ditto for appropriately trained. Perhaps the application of these requirements would be picked up through the work of CQC's audits?" Recommendation 6 states; "The Department should include the following requirements within the Regulations for public consultation: a) for the complaints function of a service provider to have adequate and appropriate expertise, resources and authority to carry out its activities effectively; and b) that all staff of service providers are appropriately trained and supported to deal with complaints (similar to a provision within the Duty of Candour Regulations)."	It would be for the service provider to document what is adequate and appropriate for its business. It would also be picked up through the assurance process and external inspections that are required under the Manx Care Act 2021.

General	"Rec 7 is important. Whilst the extent to which offloading from DHSC to Manx Care will almost certainly be questioned in the consultation, this section makes accountability lines crystal clear. Such a clause would hopefully be worded tightly enough to avoid some of the past difficulties with nailing down names and departments for accountability." Recommendation 7 states; "The Department will be held to account through its annual reporting every year to Tynwald and the Tynwald Auditor General (once appointed). Inspections of service providers will be carried out by the CQC and may highlight failings in the area of complaints handling. Such reports will be made public along with Manx Care's action plan for addressing the short comings for correction. The Department will hold Manx Care to account in implementing the action plan. The Department will also hold Manx Care to account in implementing the recommendations of the IRB(s). The Department has the power under the Manx Care Act 2021 to direct Manx Care and ultimately to remove Board members. The Department should outline its policy in relation to accountability and breach of the requirements as part of the public consultation, as outlined above, and invite feedback on the adequacy of the current approach. It is not recommended that additional consequences for breach are contained within the Regulations being prepared for November. However, it is expected that feedback will be received as part of the consultation process that could be considered as part of the policy for the NHSCS Bill."	Noted
General	what are the accepted inadequacies and who says so?	The accepted inadequacies are those that were referred to in the Tynwald debate on the motion in April 2021. If this wording is to be retained as part of the consultation paper, this will be explained and consideration will be given to ensure that the wording is such that it is sensitive towards staff members that currently handle complaints well.

General	"[Redacted] believe that this document presents a framework which has the potential to inspire confidence in service users. The consultation will provide further reassurance of the DHSC's commitment to cultural change and accountability. Whilst [redacted] agree with the proposed time frame for the urgent delivery of Stage 1 [redacted] believe that success will require a united 'push' and sufficient resource for this to happen (see also [redacted] comments under Policy above."	Noted
General	"[Redacted] has a legal obligation under [redacted] to investigate any complaint made to it by a patient detained under [redacted]. Unless this is amended by statute, the new complaints policy will need to accommodate this statutory requirement and, at present, [redacted] can see no reference to this."	Agreed
General	"in the long term legislation the "Duty of Candour" should be enshrined in the legislation as it is in the U.K."	A duty of Candour for the Department of Health and Social Care and Manx Care was brought in by the Manx Care Act 2021. The Manx Care (Duty of Candour Procedure) Regulations 2021 sets out the procedure to be followed if an incident occurs that causes harm to a service user.
General	"The Local Resolution process works very well and the timescales are flexed when common sense dictates."	Noted
General	The HSCC provide governance, however the appointments commission have decided that no one with a clinical qualification or NHS employment can provide this governance. It's akin to you saying no one with a banking or economics training can be on the Financial Services Authority regulating the finance service. The HSCC do well, but cannot scrutinise deeply because of this lack of knowledge. Perhaps the HSCC should have non island medical practice so there is no conflict."	The membership of the HSCC is not within the scope of this review.
General	In relation to the recommendation that the Department have an assurance function over complaints about Manx Care; "In terms of the first paragraph on page 3, [*redacted*] wondered whether the Department will be seen as sufficiently independent from Manx Care to handle the complaints process. although [*redacted*] realise it must be involved in addressing any serious failing on the part of Manx Care if that gives rise to a need to amend or amplify the latter's mandate."	The Department's role will be to oversee Manx Care's operation against the requirements of the mandate. The joint Independent Review Body will review the substance of individual complaints about the services provided.

General	"At the foot of page 3 the reference to the Select Committee has become mangled. [*Redacted*] think that the reference to "the 2006 Petition of Doleance/Redress" should actually be a reference to the 2006 Select Committee of Tynwald on Petition of Redress."	Agreed
General	In relation to the recommendation that the Department has an advice role; "[Redacted] wonder what you envisage as the Departmental role in advising on complaints to be. Do you have in mind imposing a duty on the Department to draw the attention of service users to the procedures by which they can pursue complaints. If so, might [redacted] suggest you say exactly that?"	Agreed
General	"on page 9, should the reference to the NHSCS Bill actually be to the Reform Bill as you have defined that earlier on?"	Agreed
General	"The first concern [redacted] have is to ensure independence for the unit conducting investigations following the initial internal review. You will note that in Tynwald Commissioner's case TCA 1904, the Department considered that [redacted], rather than the Social Care IRB should investigate the complaint because the IRB was not perceived to be sufficiently independent of the Department."	That report states that the "DHSC thought that the "preferable route" would be for me to review the complaints rather than a reference to the IRB because Mr G was unlikely to perceive the IRB to be "impartial" or "unbiased". The complainants perception of the situation does not necessarily mean that the IRB is not independent. Care is being taken to make the joint IRB as independent as possible within the current vires - it is proposed to be a stand alone body, appointed by Appointments Commission. It will be funded by the DHSC; however, it will no longer be reviewing complaints about the DHSC as the DHSC is not anticipated to be a provider of services. A more independent adjudicator is being considered as part of the longer term review of primary legislation.
General	"The very exercise you are undertaking may not inspire confidence in those aggrieved about their treatment if it is perceived to be a DHSC Departmental Review."	Noted
General	"Although you do not say so explicitly, [redacted] infer that you envisage the Regulations containing something akin to the GDPR provisions on the functions of data supervisors giving those responsible for handling complaints direct access to the highest levels in the relevant organisation and the right to act with fearless	There appear to be two issues discussed here. The first concerns compliance with GDPR obligations in the context of complaint handling, which is a matter that is being considered within the Regulations. The second is the matter of complaint handlers and investigators having the

	independence in dealing with problems. Have [redacted] understood correctly?"	appropriate level of authority to pursue their inquiries without obstruction. It is intended that there will be a requirement within the Regulations that the complaints function of a service provider should have appropriate authority to be able to act independently in considering a complaint.
Handling of the complaint by the IRB	Indicated a preference for "statute" in relation to whether to put in statute or to alternatively make it subject to approval of the Department, COMIN or Tynwald for the standard considerations for IRB to decide whether the complaint should be considered further.	Suggested standard considerations to be within Regulations: (a) the complainant is not directly affected by the subject matter of the complaint; (b) the service provider has reached a resolution with the complainant which is fair and reasonable in the circumstances; (c) the complaint has been the subject of a decision on the merits in proceedings in any court; (d) the complainant has or had a right of appeal, reference or review to or before a tribunal constituted by or under any enactment; (e) the complaint has been properly considered under any enactment or arrangement providing for the resolution of disputes or the investigation of complaints; (f) the complaint would more suitably be dealt with by a court or under an enactment or arrangement referred to in sub-paragraph (e); or (g) the complainant has not exhausted the service provider's internal complaints procedure.
Handling of the complaint by the IRB	Suggested that the IRB should be required to explain the reasons "why" when a decision is made not to consider the complaint any further.	This is already a statutory requirement and will be retained.
Handling of the complaint by the IRB	"There should be no discretionary power for the IRB… the requirements for considering complaint should be laid out in regulations and not up to the current Governors personal opinion of the complainant."	Agreed that the requirements for considering a complaint will be included within Regulations, although the use of discretion on a justified basis could be included for in instances where the IRB takes a decision that is not consistent with the established approach, but reasons are set out in writing for the departure from precedent. This would most commonly occur in situations where an adverse impact might arise for a complainant as a

		consequence of a rigid application of 'rules'.
Handling of the complaint by the IRB	Whilst there is no problem with setting timescales they do need to be realistic. A case can involve a Convenor studying hundreds of pages of sometimes disorganised and sometime illegible documents. Speeding up the process of review can only be achieved if Manx Care resolves it keeping. At the start of addressing a complaint the Convenor should expect to receive an ordered file containing all of the relevant data.	It is intended to include a requirement that the service provider must provide the information in good order and by the time requested as part of the Regulations.
Handling of the complaint by the IRB	Complaints to the IRB can often be made in parallel with other procedures; notably (but not limited to) Inquests. Whilst the current Regulations deal with the issue of a complainant who takes legal action against DHSC (and now Manx Care), they are silent on other legal processes. The current provisions should be retain ed but should be strengthened to provide primacy for the Courts. The Financial Services Act 2008 deals with the primacy of the High Court in Schedule 4. It is suggested that the new Regulations should provide a similar power to any Court. This power is particularly relevant to the Coroner of Inquests who should have clear primacy.	We agree that the primacy of the judicial system is an accepted principle which should be reflected in the Regulations.
Handling of the complaint by the IRB	If fixing deadlines it is suggested that there should be an "in exceptional circumstances" extension clause at the discretion of the IRB	This is planned to be contained within the Regulations
Handling of the complaint by the IRB	the discretionary power for the Health IRB to decide whether a complaint should be considered further or rejected should be based on standard considerations in the Regulations and it is suggested that any decision to reject should subject to an appeal process to the Department.	This is planned to be contained within the Regulations
Handling of the complaint by the IRB	In relation to a timescale for a convenor to consider a complaint; "In paragraph 6 on that page, [redacted] would suggest that you make some provision for exceptional cases. Having a single time limit for everything is fine and simple, but it often does not work in practice. You need to provide some form of escape valve for the complex cases, some of which will certainly arise."	Agreed

Handling of the complaint by the IRB	"In point 5 on that same page, you suggest a formal response be required within 20 working days. [Redacted] experience [redacted] suggests that this is an unrealistic expectation in the Manx context. Similarly in point 7 you make the point your proposed extension to 12 months for complaints is in line with UK provision, which is true but overlooks the Manx context referred to above."	The Local Authority and National Health Service Complaints (England) Regulations 2009 that apply in England make provision for complaints to be responded to within 6 Months. This was a response to the same 20 day target embedded in previous regulations that were never met by NHS bodies. The principle is that NHS bodies respond as quickly as possible within that 6 Month timeframe, and indeed many set corporate targets for different kinds of complaints dependent upon their complexity. However, it is not considered that a move to such a long timeframe would be acceptable in the Manx context. Tynwald has asked that the complaints process and timescales are set within the Regulations, and have commented that there is a lack of statutory timescales for review of complaints and where they are current timescales are overly long and appear insensitive to patients needs. Therefore, it is intended to keep the 20 day timeframe for a service provider to respond to a complaint. Many straightforward complaints can be dealt with within this timeframe. For any that are more complex and require additional investigation the response after 20 days will allow the service provider to explain to the complainant why this complaint will take longer to investigate and manage their expectations by giving a revised timescale within which a response will be received.
Investigation by the service provider	"Timescales need to be outlined and adhered to" in relation to requirement to keep complainant informed about investigation.	Where the question of keeping complainants informed is concerned, it is not considered that a commitment to set in stone a requirement for people to be kept informed would be the best option. This is because no two complaints are the same and the investigative process can move quicker or slower in each case (e.g. the need to interview a key witness who is not available through leave or sickness for a period of a month or more). People should be kept informed about the investigation on

		a regular basis relevant to the facts of the case and the need for a proper consideration of the matter subject to complaint. The proposal is that the complaint response must be issued within 20 working days. If the response is not issued within 20 working days then the service provider must notify the complainant of the reason for this and advise what the revised timescale for when a response can be expected to be received. In addition, it is proposed that there will be a requirement for the complainant to be kept informed about the progress of the investigation on a regular basis.
Investigation by the service provider	"It is noted that a firmer requirement to keep the complaint informed will be required but this should include a requirement for *meaningful* updates and strict timescales, say every 14 days after the 20 day timescale has been breached."	The current proposal is that the complaints manager must take steps to keep the complainant informed about the progress of the complaint. The response must be issued within 20 working days. If the response is not issued within 20 working days then the service provider must notify the complainant of the reason for this and advise what the revised timescale for when a response can be expected to be received. The requirement for meaningful updates will need to be part of the behaviour and systemic change in culture that will be encouraged through advocacy for the adoption of best practice standards.
Investigation by the service provider	"Participation in complaints investigations and reviews by those involved has to be mandatory, even by consultants… Roles of Consultants and Medical Director(s) should be considered in the context of the process and follow up learning."	Agreed, this will be part of the behavioural and systemic change in culture that will be encouraged through advocacy for the adoption of best practice standards.
IRB report of their findings	In relation to reporting by the IRB, suggested they should include details of; "No of complaints, timescale for resolution, actions taken, feedback"	Agreed
Learning and improvement	In the proposed new section about learning from complaints, suggested adding requirements for the service provider to; - Provide feedback to the complainant on changes to ensure they feel their complaint was valued, and - Provide feedback forms provided to complainant at end of every process (Manx care and IRB) to ensure quality. Include feedback in reporting process.	A change has been suggested to the response section of the Regulations to require that the response to the complainant includes a description of the action taken as a result of the complaint, which maps to the 'you said we did' model of customer relations. Where feedback forms are concerned, broader wording will be

		included which requires service providers to ensure that appropriate mechanisms are in place for complainants to share feedback about their experience of the complaint handling process. The mechanism for receiving feedback should be for left to the service provider to decide as it is operational.
Learning and improvement	In relation to Manx Care's action plan for addressing failings in complaints handling identified in inspections; "timescales for correction" of the failings should be included in the inspection reports.	Timescales for correction are included in the proposals.
Learning and improvement	In relation to regular reviews to establish any links between complaints and duty of candour incidents; ""Regular" review is not sufficient, fixed timescale of reviews."	The intention is for the Regulations to require this on a quarterly basis, for the service provider to take any action identified by the review and for the service provider to report on that action in its annual report.
Manx Care's assurance of complaints about commissioned service providers	This Role needs to be substantial - at present small contractors such as GP practices do not presently investigate complaints properly. There is a lack of independence of investigators. It is vital that the person undertaking an investigation was not party to delivering the service complained about. The challenge with small contractors such as GP practices and dental practices is to achieve any real independence for the investigatory role. As a result initial decisions are "rubber stamped" and the complaint ends up at the IRB	It is suggested that this is dealt with through both the DHSC's and Manx Care's assurance framework i.e. that Manx Care are taking appropriate steps to address this concern. Embedding the detail of such a role in Regulations is fraught with anomalies due to the quite differing size and scale of providers.
Meeting the complainant or representative	"Recommendation 1 of 33/06 was fairly descriptive in its description of the process. (c)A meeting with Hospital Complaints Manager to discuss the complaint; (d)A further meeting if required with clinician(s) to provide an opportunity for questioning, accompanied by someone chosen by complainant; DHSC are currently suggesting that the complainant have the opportunity to meet a "relevant health care or social professional". This is a generic term and can include any number of people who are not "clinicians"." Details [redacted] personal experience that the meeting was ineffective because information was unavailable and it was complaints and management staff without any of the staff who were involved in the care of the deceased. "Meetings should be attended by a clinician familiar with the case and able to answer	The meeting required by (c) will be included within the Regulations. The wording suggested for inclusion to address (d) is "offer the complainant an opportunity to meet with a relevant health or social care professional that is familiar with the nature of the complaint and is qualified to answer questions about the service user's care that has resulted in the complaint". Clinician is a very health focussed term. The term health or social care professional is broader and more inclusive of social care practitioners.

	questions. It is appreciated that nurses in attendance may be excellent nurses but they are not qualified to give opinions on technical cancer care, that is the role of a Doctor."	
Meeting the complainant or representative	Meetings with complainants must be minuted (or recorded)	Agreed but this is operational detail to be contained with service provider standard operating procedures.
Meeting the complainant or representative	"It would be useful to have some clarity as to what the policy is intended to be about meeting staff to discuss the outcomes of a complaint. To do this at the start of the process may avert protracted process if people feel listened to and get a good explanation early on, and possibly also an action plan for improvement… [redacted] think there should be two meetings offered, one at the outset to hear the complainants story, and one, the resolution meeting after a full investigation to answer the complaint… with the intention of meeting the complainants reasonable expectations and giving a satisfactory explanation of those that cannot be met... Complainants should be given more information about remedial plans, progress and where necessary any staffing implications."	The Regulations are intended to contain provision that the need to meet with complainants must form part of the complaint handling process. Exactly when, and how often this should occur, is principally an operational matter (i.e. in more serious complaints it would be advisable to meet with the complainant at the outset in order to define their complaint and agree the investigative scope, then as part of the investigation, and again at the end to discuss the outcome and action plan).
Overall 2 step complaints process	"Recommendation 2 procedures are to be welcomed and will no doubt be subject to much debate on timescales. [Redacted] is pleased to see that there will be a process (9) that seeks to establish links with duty of candour incidents (please also refer to our Duty of Candour consultation response dated 15th January 2021)."	Noted
PALS/advocacy	"PALS - excellent." "[Redacted] still see a place for [redacted] to provide independence. [Redacted] help complainants to generate a complaint, construct it in writing ([redacted] do not write anything - must be in their own words). It must be written by complainant or someone with written authority to act on their behalf. Usually a simple timeline is best structure highlighting areas of concern and most important , the outcome that is sought."	Agreed - no change required
Public consultation	"The public consultation has to be free of leading questions."	Agreed

Public consultation	In relation to *a wide question to ascertain what the public currently thinks is and isn't working;* "Asking what the public thinks is and isn't working is indeed a wide question. How will this be done? Will a consultation question give some background information or examples? Patient/Service User Reps are consulted but do they exist yet and will their networks have the capacity to provide useful answers?"	It is agreed that this question may be too wide for a consultation on revised Regulations as the responses elicited will likely be personal accounts of issues faced in relation to complaints handling that will not be able to be addressed directly through legislation and so not be an effective engagement exercise. It is intended that the consultation paper will ask specific questions about the accessibility of the information provided to complainants and the best way to disseminate this information to help inform the future arrangements. The Department intends to recruit independent patient and service user representatives in quarter two but in the meantime service users that have recent experience of the complaints process have been consulted as part of this process.
Public consultation	Consider referring to either DHSC or The Department consistently so long as it is clear what is meant.	Agreed that this needs to be consistent in the consultation paper.
Public consultation	"For the purposes of public consultation [redacted] recommend that more clarity is provided about definitions of support and advocacy to limit possible confusion between the two when considering Patient Advice and Advocacy."	Agreed
Public consultation	In regards to options for independent adjudicator or ombudsman; "The options will need explaining clearly to a public readership for the consultation. The whole document needs reviewing with this in mind so that no difficult words, acronyms or jargon remain unexplained."	Agreed
Public consultation	"In the third paragraph on [page 2] you say that "It has been stated during the motion's debate in Tynwald that complaints are not being appropriately handled to *support* those who seek redress and learning is not taking place as a result of complaints." [[redacted] emphasis]. This is an unfortunate choice of word given that the review of a complaint is supposed to be an impartial and dispassionate exercise. Complaints certainly need to be handled sensitively, but the process needs to be fair both to the complainant and the professionals involved. "Support" suggests a bias in favour of the complainant. [Redacted] would suggest	Agreed

	talking instead about meeting the legitimate concerns of complainants."	
Public consultation	"The second full paragraph on page 2 of the paper is distinctly confusing in referring to two different things as "Stage 2" (albeit that in one case the word appears and in the other Arabic numeral). Readers will be puzzled as to what is going on. It might be clearer to refer to "point 2" in respect of the resolution and "stage 2" in relation to the legislative changes you envisage making."	Agreed
Public consultation	"Extend the remit (and resources) of the existing Tynwald Commissioner for Administration, whose function is to investigate complaints from members of the public who claim to have sustained injustice or hardship as a result of service failures by, or the administrative actions of Government Departments, Statutory Boards and local authorities (including action taken on their behalf), to cover investigation of health and social care service complaints." (as opposed to; "of Government Departments (including action taken on their behalf) and Statutory Boards")	Wording change suggested for the consultation paper.
Public consultation	""PALS" needs unpacking. Although it may be obvious to Departmental insiders, it will be lost on the public."	Agreed to explain more within consultation paper.
Public consultation	"Reference to IRB/Independent Adjudicator/Convenor and other terminology/names throughout the document could be confusing for the public and may be better either standardising or explaining the difference."	Agreed
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	In relation to annual reporting to Tynwald by DHSC and also regular reporting by Manx Care to DHSC; "Fixed statutory timescale, say 3 months after financial year end". On reporting by an independent adjudicator, suggested "Annually to Tynwald and also publish on DHSC website" and "Tynwald, the issue with DHSC appointing is the perceived lack of independence"	The intention is for Regulations to require (a) DHSC reporting to Tynwald within 6 months of the financial year end to be in line with the annual report required under the Manx Care Act and to publish the reports on their website and (b) IRB report annually (within 3 months of end of financial year) also to Tynwald via DHSC.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"An annual report for Tynwald is required but it must be set timescales, i.e. 3 months after financial year end… the timescale for Candour reports was not included in the new legislation passed in April 2021 despite promises to the public. This was very disappointing and should be corrected in November 2021."	Timescales for the reports under the Manx Care (Duty of Candour Procedure) Regulations 2021 are for Manx Care to prepare a report within 3 months and then to publish it without undue delay. The vires within the Manx Care Act 2021, under which the Regulations are made, means that the reports could not be required to be published within a set timescale. Further changes to the Manx Care

		(Duty of Candour Procedure) Regulations 2021 are not included within this review of complaints legislation. The timescales for the complaints reports are suggested to be set at 6 months after the financial year end in order to be in line with the annual report required under the Manx Care Act 2021.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"The time taken to respond substantively to complainants should be monitored and reported on to assess whether the 20 day target is actually being met."	Agreed
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	IRB Reports should be subject to statutory confidentiality. Inevitably they contain highly sensitive personal data about the complainant and health professionals. The Regulations should allow for publication of summarised reports (at the discretion of the DHSC after consultation with the IRB) which do not identify individuals.	Agreed - it is intended that the Regulations will allow the information gained by the Review Body for the purposes of the investigation and reporting to be subject to statutory confidentiality. There is already a requirement that "The 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 to whom it relates". This confidentiality provision will be retained.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	The IRB should report to Tynwald to include an anonymised summary of complaints finalised and rolling RAG report on all outstanding recommendations to Manx Care and DHSC	It is agreed that the IRB should report to Tynwald and it is proposed that this will be required within the Regulations (independently if possible or more likely through the DHSC).
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"[redacted] presume the system will also take into account the severity of impact of the complaint. Service standards and reporting should reflect this."	Agreed

Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"How redress can be expressed. Publicly?"	Redress will be expressed directly to complainants within response letters and the annual reports will contain information about the actions taken as a result of complaints.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"Manx Care should develop and publish their processes for dissemination of information on complaints throughout the whole organisation."	Agreed this should be part of the operational policy, which should be published.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"Does the role of the media / communication team have any part to play in relaying information to the public?"	There will be a statutory obligation for DHSC to report annually and publish the report on its website. Members of the DHSC's communication team will be able to signpost comments on social media to published reports.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	"Reporting framework to be agreed between Manx Care, DHSC and Tynwald to evolve over time, like Chief Constable's Report."	The DHSC's Quality and Safety Committee and Mandate Assurance Committee will be both requesting quarterly KPI's on complaints. Annual reports to Tynwald will be made. It is agreed that this is likely to evolve over time.
Reporting requirements for the DHSC, Manx Care, commissioned service providers and any independent adjudicator	In regards to *regular reporting from Manx Care*; "Action (g) by The Department could be a recipe for drift if 'regular' is not defined."	The timescale will be defined within the Regulations
Requesting a review by the IRB	"current regulations state if DHSC/Manx Care have not completed the complaint in 6 months then the complainant can escalate to IRB. Can this be retained?"	Yes this will be retained
Requesting a review by the IRB	"The changes in time scales for making complaints and requesting IRB involvement are reassuring and are strongly supported."	Noted

Requesting a review by the IRB	"there is some concern that some conditions, particularly serious depressive illness or psychosis can take many months to recover and that, for a few patients, capacity to make a complaint about something that took place earlier in their treatment may not be regained until well into or even after the 12 month period. Although the numbers may be small these may be very vulnerable individuals and it would be helpful if there were some provision for the 12 month period to be extended under certain circumstances (e.g. 12 months from when documented capacity was regained)"	Agreed, it is suggested to retain flexibility at the discretion of the Chair of the joint IRB
Requesting a review by the IRB	In relation to discretionary powers of IRB and standard considerations; "[Redacted] would counsel against the standard considerations being fixed by the Department. [Redacted] think they would be better being settled by COMIN and approved by Tynwald, thereby securing some further independence."	This would fit with the standard considerations being set within legislation and approved by Tynwald, which appears to be the majority view.
Requesting a review by the IRB	"At the head of page 4 you assert that "the timescale [should be] 12 months in line with internationally accepted best practice". [Redacted] accept that both the Parliamentary Commissioner in England and the Scottish Public Services Ombudsman ("the SPSO") apply a 12 month time limit, but their processes are somewhat different, even though the Tynwald Commissioner for Administration Act 2011 was broadly based on the legislation which established the SPSO. Your predecessors in the Chief Secretary's Office (as it then was) made a conscious decision in 2010 to apply a shorter time limit for complaints under what became TCAA 2011 because of the potential difficulties in recovering accurate data and documents after 12 months: memories also fade with remarkable speed."	The timescales within the Tynwald Commissioner for Administration Act 2011 (TCAA) and for the Financial Services Ombudsman Scheme within the Financial Service Act 2008 (FSA2008) have been further considered. TCAA - "The Commissioner must not consider a complaint made more than 6 months after a final decision of the listed authority has been notified to the complainant." Schedule 4 of the FSA2008 - "You must bring a complaint to the Scheme within six years of the act or omission which led to your complaint and within two years of when it should have come to your notice if you weren't aware of it immediately". After consideration, it is not felt that the '"accurate data" and "fading memories" argument is sufficiently persuasive. The 12 month timescale adopted by all ombudsmen and advocated by the Ombudsman Association reflects a view that the timescale needs to accommodate a range of variables where the needs of the public are concerned, e.g. some people are not initially aware that an event has occurred for which the making of a complaint is a legitimate response, and some (particularly in

		health and social care) will have impediments or events that reasonably delay their ability to make a complaint to an ombudsman. Therefore, the 12 month timescale will be set within the Regulations for consultation.
Structure and makeup of IRB	"[redacted] have heard that there are question marks over the legal status of the SS IRB. [redacted] do not know if this information is correct however it needs to be resolved if true."	The establishment provisions for the SS IRB are set out in Social Services Act 2011 and Regulations made under that Act. This will be amended in order to form a joint IRB as part of the changes being proposed.
Structure and makeup of IRB	"A single IRB must be the way forward as it takes away complexity and saves time as well as simplifying training and expectations. [Redacted] are concerned that this has not been addressed much earlier than now." "In regards training for IRB; "Of the options for addressing training [redacted] all agree that the second option of IRB members having CPD hours would provide more flexibility and better training pathways, with consequential likelihood of improved compliance. Members of IRB must be competent as a result of relevant training."	Noted
Structure and makeup of IRB	"[Redacted] agrees a single Independent Review Board dealing with both Health and Social Care at a single point of access is desirable. Concerns have been expressed that the volume of complaints from both sources together may exceed what a single IRB could cope with."	It is agreed that streamlining below the current provision would be unwise given the current dissatisfaction with timescales expressed by many complainants. It is therefore intended that the joint Independent Review Body will consist of 9 members, which is equivalent to the total number of members currently appointed to the Health IRB and the Social Services IRB.
Structure and makeup of IRB	In relation to removing the Department's role in reviewing complaints and extending the remit of the IRB to cover care, safety, quality and clinical matters etc.; "In paragraph 7 on that page, rather than seeking to amalgamate the processes, [Redacted] would suggest that a comprehensive overhaul is required. Once again, the role of the Department as the arbiter of complaints may justifiably be criticised for a lack of independence."	Agreed that this requires a full review. Anything that cannot be addressed through the Complaints Regulations review in the shorter term will be picked up as part of the National Heath and Social Care Services Bill.
Structure and makeup of IRB	"[Redacted] suggest that the funding of the IRB should not be in the Department's hands but with the Cabinet Office in order to insulate it from any suggestion of political	Since 1 April 2021 the Department's role has changed so that it is no longer a provider of health or social care services; therefore, the IRB will not have any

	pressure from a body which it might be criticising."	remit over complaints about the Department. As a result, it is considered that the Department funding the IRB would not cause any conflict of interest.
Structure and makeup of IRB	"There is a reference to the new ombudsman should be a separate legal entity: is it accepted that the IRBs do not currently have the status of legal entities?"	To be considered in setting up any new Review Body
Structure and makeup of IRB	"[Redacted] is primarily concerned about how the constitution of the two independent review bodies will be combined given the vast difference in the two, and believes that it will be vital that this is set out prior to public consultation. Specifically, the Commission notes that the constitution of the Social Services IRB is set out in primary legislation rather than regulations."	Noted - changes can be made by Regulation.
Structure and makeup of IRB	"If the independent review bodies are combined what impact will this have on workloads and the number of members required for the IRB?" "It will be important to understand the potential level of workload and therefore the size of the body should be reflect this"	It is agreed that streamlining below the current provision would be unwise given the current dissatisfaction with timescales expressed by many complainants. It is therefore intended that the joint Independent Review Body will consist of 9 members, which is equivalent to the total number of members currently appointed to the Health IRB and the Social Services IRB.
Structure and makeup of IRB	"[Redacted] notes the use of the term "convenor" in relation to the Health Services IRB. Such a role does not exist in the Social Services IRB." "What will the role of the Convenor be and how will a 'Convenor' be selected?"	It is not proposed to continue with the term convenor as it adds an additional layer of complexity that could cause confusion for members of the public. Currently, all members of the Health Services IRB are convenors and consider complaints.
Structure and makeup of IRB	"The document makes reference to drafting regulations for consultation on page 7, including inter alia membership requirements. [Redacted] would suggest, based on [redacted] experience, that details relating to what might be described as the "person specification" should not be set out in statute or regulations."	Agreed
Structure and makeup of IRB	"If the process is extended to cover all providers, what services are covered by the term 'private entities'? (private healthcare, nursing homes, etc. . . .)"	Any provider of a health or social care service on the Island.

Structure and makeup of IRB	"Experience leads [redacted] to say that initial and ongoing training is essential and should be planned and funded for those appointed to this role." "A remuneration model will need to be considered to tie in with the commitment to this role"	Noted
Structure and makeup of IRB	"[Redacted] feels it would be beneficial to have flow charts for the existing operation of both bodies to be able to consider the most effective parts of the process"	Noted - this will be requested from the IRBs.
Structure and makeup of IRB	"Will executive/administrative resources be made available to enable the body to function? E.g. composing 'Standard considerations' for acceptance of a complaint, Annual Report, undertaking investigations, preparation of reports, minutes of meetings?"	Yes, consideration is being given to how this will be made available and the necessary independence of persons providing such a function.
Structure and makeup of IRB	"The Ombudsman scheme would change the nature of the complaints process so if it does become a 'long term' policy, should the operation of the IRB be tailored towards this?"	Changes are being suggested to the operation of the IRB as part of a journey towards a independent adjudicator.
Structure and makeup of IRB	"The document seems to indicate that the Appointments Commission would have a role in making appointments to the combined IRB and it would offer the following benefits should this be the case: - It 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 - It has a systematic and consistent approach to appointing to independent bodies across all sectors across government - It is broadly familiar with candidates who typically put themselves forward for such appointments - It is a cost effective independent body - It has a diverse membership - It already has the responsibility of appointing to the Social Services Independent Review Body"	Noted

Technical points for Regulations	It is suggested that the new Regulations should deal "head-on" with (a) frivolous or vexatious complaints. Manx Care (including its contractors) and the IRB should be specifically empowered to reject a complaint or terminate the handling of a complaint on the basis that it is:- (a) frivolous or trivial; or (b) vexatious; or (c) it has been pursued in a manner that has been vexatious, oppressive or threatening; and, after written warning to desist, it continues to be pursued in such a manner.	This is contentious as some people could perceive it as an attempt to further gate access to the complaints processes. We accept that some complainants can present challenging behaviours, but caution is needed as many patients and service users are 'damaged' by their experiences and this can manifest in the way they present their concerns and grievances. These considerations would be better addressed outside of the Regulations through a protocol between Manx Care/the IRB and the complainants that sets out respective rights, responsibilities and expectations between the parties. This is something done successfully by the SPSO and PHSO.
Technical points for Regulations	The new Regulations which, inter alia, merge the two IRB's will require transitional measures which should include:- (a) cases under investigation transferred seamlessly into the new IRB with the same Convenor; (b) Convenors duly appointed to the existing IRB's to continue on the new IRB for the duration of their term.	It is agreed that the Regulations will need to contain transitional provisions to ensure that complaints that straddle both bodies are dealt with seamlessly. However, it is intended that the membership requirements for the joint IRB will be different to that of the current IRBs and therefore, the current members may need to reapply for reappointment.
Technical points for Regulations	"Please define complaint somewhere as there has been gaming in the past as to whether a complaint is a 'concern' or a complaint - so not lodged appropriately. e.g. verbal = concern, written = complaint only if the word 'formal' appears etc.!!"	It is not intended that the Regulations will contain a definition of complaint. The usual dictionary definition should apply here given that there is no definition of complaint in the primary legislation. However, clarification in relation to oral complaints being considered under the Regulations will be added. The operational application of the Regulations should contain a definition to ensure consistency.

END
