Explanatory Memorandum to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

This Explanatory Memorandum has been prepared by the Health and Social Services Directorate General and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. I am satisfied that the benefits outweigh any costs.

Edwina Hart AM MBE
Minister for Health and Social Services
7 February 2011

1. Description

1.1. The Regulations make new arrangements for the notification and consideration of and response to concerns notified by patients in respect of services provided by or under arrangements with the National Health Service in Wales.

1.2. A concern is defined as a complaint, a notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation. The Regulations also introduce the concept of “redress”. They place an obligation on a Welsh NHS body to consider, when it is notified of a concern that alleges harm has been caused or may have been caused, whether or not there is a qualifying liability.

1.3. Part 7 of the Regulations contains provisions detailing how the redress arrangements will operate when a Welsh NHS body enters into arrangements with an NHS body in England, Scotland or Northern Ireland.

2. Matters of special interest to the Constitutional Affairs Committee

2.1 These Regulations are the first to be made under the NHS Redress (Wales) Measure 2008. As such they are subject to the affirmative resolution procedure. They also draw on other powers, and these are detailed in the next paragraph. The Regulations will come into force from 1 April 2011, except for the provisions falling within Part 7, which will come into force on 1 October 2011 to allow for further details to be agreed with the Department of Health.

3. Legislative background

3.1 The relevant legal powers are contained in Sections 113, 115 and 195 of the Health and Social Care (Community Health and Standards) Act 2003, sections 187 and 206 of the National Health Service (Wales) Act 2006 and sections 1 to 7, 9, 11 and 12 of the NHS Redress (Wales) Measure 2008. These are powers of the Welsh Ministers. All of the necessary powers are in force. Some were commenced recently and these are outlined below.

3.2 The relevant sections of the NHS Redress (Wales) Measure 2008 are commenced by the NHS Redress (Wales) Measure 2008 (Commencement) Order 2011. The commencement order was made on 2 February 2011.

3.3 Section 113(2), (3) and (4) of the Health and Social Care (Community Health and Standards) Act 2003 is brought into force, to the extent that it

is not already in force, by the Health and Social Care (Community Health and Standards) Act 2003 Commencement (Wales) (No. 5) Order 2011. The commencement order was made on 2 February 2011.

4. Purpose and intended effect of the legislation

4.1 The Welsh Assembly Government's *Putting Things Right* project looked at the way in which the NHS in Wales handles concerns and has made recommendations for how this could be done more effectively, using common methods of investigation, proportionate to the issue in question leading to appropriate remedies for patients and service users. As part of the work, the Welsh Ministers sought and obtained framework powers in the NHS Redress Act 2006 which were converted into legislative competence enabling the NHS Redress (Wales) Measure to be passed in 2008. The powers in the Measure enable Welsh Ministers to make Regulations which allow for redress to be provided in circumstances where there is a qualifying liability in tort in relation to the provision of qualifying services. Redress may encompass apologies, explanations, action plans, remedial treatment and, if appropriate, financial compensation.

4.2 A more accepting and supportive culture needs to be encouraged when it comes to dealing with concerns about treatment and care, with staff at all levels being encouraged to apologise for adverse outcomes and to offer explanations for why they have arisen. NHS organisations will need to build on work already underway in developing an ethos throughout the organisation in which:

- A patient/user focussed, rather than process driven, approach is evident throughout the organisation which also empowers people to raise concerns and have them dealt with as soon as they arise.
- The emphasis is on resolving concerns in a timely fashion, openly and honestly – a philosophy of "investigate once, investigate well".
- Staff can be confident that investigations will be fair and impartial and that they will be supported throughout the process.
- Learning from concerns and errors drives quality improvement and reduces adverse events, and avoidable harm to patients/users.

4.3 A significant strand of the work has also looked at the level of support that should be available to people wishing to raise a concern, and also for the staff involved. The work builds on the National Patient Safety Agency (NPSA)'s *Being Open* policy that has already been widely introduced in the NHS in Wales and which was re-launched by the NPSA in the autumn of 2009.

4.4 By introducing legislation, the Minister is seeking to make the approach to handling concerns consistent across the health service in Wales. This will improve the experience of patients and make systems more accessible for people who may not otherwise raise their concerns.

A detailed explanation of the effect of the Regulations is at Annex 1.

5. Consultation

5.1 There has been a significant amount of engagement with stakeholders undertaken in the development of the policy. The Putting Things Right Project Board was drawn from across the NHS, and also included the Royal College of Nursing and the Public Services Ombudsman for Wales. The working groups which made recommendations to the project were drawn from across a range of areas, including legal firms, Community Health Councils and the wider NHS. Meetings and engagement events were held with:

- patient groups (i.e. Eiriol Mental Health Carmarthenshire; Swansea and Gwent Patient Involvement groups; Age Concern Cymru);
- staff interest organisations (i.e. RCN; BMA Wales; Medical Defence Union; Medical Protection Society);
- stakeholder groups (i.e. Community Health Council advocates; Sensory Impairment Working Group).

5.2 An earlier draft of the Regulations was subject to a full 12 week consultation from 11 January 2010 until 2 April 2010, which generated 119 responses. A consultation report was issued on 2 August 2010. A further short technical consultation was held between 6 and 30 September 2010, on a revised version of the draft Regulations. The short consultation covered two specific aspects relating to the financial limits for compensation for redress and the cross border application of the redress arrangements, and 16 replies were received.

5.3 A number of amendments have been made to the Regulations to take account of the comments received during the consultation. These include the following:

<u>Consultation held between 11 January and 2 April 2010</u>

- Amendments have been made to the Regulations (Regulation 23) to strengthen independence in the process and involvement of individuals, namely:

    - the more effective and routine involvement of the person raising the concern;
    - the need to consider the securing of independent clinical or other advice and
    - the use of alternative means of resolving a matter using independent services such as mediation or facilitation.

- Further amendments (Regulation 15) have been made to clarify the time limits for bringing forward a concern as well as the need to communicate clearly and regularly with those raising a concern if the investigation is taking longer than it should (Regulations 24 and 26).

- The Regulations are now clear that the NHS Redress element of the arrangements does not apply in primary care (Definitions and, for example, Regulations 23(1)(i), 23(2), 25, 34, 35, 37, 38 and 39 where obligations in respect of NHS Redress are only placed on NHS bodies).

- An amendment has been made to suspend the limitation period from the date that the concern was first notified to the NHS organisation (Regulations 30 and 45).

<u>Consultation held between 6 and 30 September 2010</u>

- The Regulations are now clear that the NHS Redress element of the arrangements does not apply to independent providers (Definitions and, for example, Regulations 23(1)(i), 34, 35, 37, 38 and 39 where obligations in respect of NHS Redress are only placed on NHS bodies).

- An amendment has been made to set the overall financial limit for any compensation for redress to £25,000 (Regulations 29 and 44).

- The Regulations now set out more clearly how the redress arrangements will operate in terms of care provided by an NHS provider in England, Scotland or Northern Ireland (Part 7).

6. Regulatory Impact Assessment (RIA)

7. Options

7.1 The following options were considered:

Option 1: Do nothing and leave the current arrangements to develop at their own pace

Option 2: Introduce alternative arrangements through guidance, or Directions falling short of regulations

Option 3: Set out the arrangements in new legislation

Option 1 – Do nothing

7.2 The current arrangements for handling concerns in the NHS in Wales (including complaints, claims and incidents) are fragmented and not providing the opportunity to make best use of resources or to learn lessons as effectively as possible. In addition, the arrangements are not easy for people to understand and access and this needs to change. There is also still a defensive culture in some parts of the NHS which often means that patients have not had a good experience when raising their concerns locally.

7.3 *Complaints* are governed by a series of Directions to NHS organisations and thus a degree of consistency is to be expected in their handling. However, in practice there is considerable variation in quality in both investigation and response, and dissatisfaction amongst complainants with both local resolution and independent review stages. This can be evidenced to a degree by the increase in recent years of health service complaints referred to the Public Services Ombudsman for Wales.

7.4 *Clinical negligence claims* are handled in accordance with the Civil Procedure Rules and as part of this, organisations and patients engage in a more litigious process, whereby fault is established, denied or admitted with the involvement of legal and other specialist advisers. There is currently no requirement for NHS bodies to learn lessons from these cases, although the Pre-Action Protocol for the Resolution of Clinical Disputes (which is part of the Civil Procedure Rules) does have as one of its "good practice commitments" a recommendation that healthcare providers should use the results of adverse incidents and complaints positively as a guide to how to improve services to patients in the future.

7.5 *Incidents* occur regularly and range from those where no harm has come to a patient, through to death being caused. Whilst reporting of incidents is a requirement under the Healthcare Standards for Wales and is at an all-time high in Wales, this evidence of an emerging culture of openness needs further impetus if it is to grow and develop. It is necessary to deal with incidents more consistently, and to seek to deliver appropriate outcomes and remedies in line with those that are considered as a result of complaints and claims.

7.6 Doing nothing means that we will miss the opportunity to bring together these disparate areas and will leave the current systems to develop at their own pace and in relative isolation. A Group led by the Public Services Ombudsman for Wales has recently made recommendations to the Assembly Government for the adoption of an all-Wales system for the handling of complaints, largely based on the proposals which emerged in respect of the health service as a result of the Putting Things Right project. However, we believe that whilst the proposed arrangements for the public sector would secure benefits in the NHS in Wales, because of the specific nature of NHS issues, often involving clinical decisions and emotive personal issues, that it is not sufficient to rely on these general arrangements alone and that a statutory process should apply.

Option 2 – issue guidance or Directions, falling short of legislation

7.7 The Directorate General has already issued interim guidance to the NHS in Wales on the handling of concerns, to enable organisations to use the NHS restructure as a vehicle for making organisational change. Whilst it would be possible to rely on guidance and directions to make changes to the system for investigating concerns, it is only possible to implement the policy in respect of NHS redress by utilising the regulation making powers contained in the NHS Redress (Wales) Measure 2008.

7.8 In addition, the Health and Social Care (Community Health and Standards) Act 2003 contains specific regulation making powers in respect of NHS complaints and it makes sense to use these specific powers rather than issue new directions using our general direction making powers.

Option 3 – Set out the arrangements in new legislation

7.9 The Assembly Government wishes to ensure that the NHS in Wales responds consistently to things that go wrong, with a system of proportionate investigation and appropriate remedies. With regard to the NHS redress policy, the regulations place an obligation upon NHS bodies in Wales to consider, when a concern is notified that alleges a patient has or may have suffered from harm, whether there is a qualifying liability. The intention is to place a duty on NHS bodies in Wales to be pro-active and consider whether any of their acts or omissions could have caused harm to a patient. If the NHS body is of the opinion that there is or there may be a qualifying liability the redress process under Part 6 of the Regulations must be triggered. It is considered important that where an NHS organisation may be at fault this is investigated and if harm has been caused to a patient as a result of the negligence of an NHS body an admission of liability is made and appropriate "redress" including, where appropriate, financial compensation is offered to the patient. This avoids defensive action which can result in protracted legal proceedings which can result in higher legal costs being paid by NHS bodies. Placing the NHS under a duty to consider these situations will ensure that we move away, in appropriate cases, from the current adversarial arrangements into more proactive situations which are better for patients and staff because they are not overly prolonged and where more investment is made in the conduct of the investigation. The regulations (regulation 12(7)) will also require NHS organisations to be open with patients if a member of staff notifies a concern and initial investigations reveal that an incident has resulted in moderate or severe harm or death to a patient. This goes further than the current recommendations contained in National Patient Safety Agency (NPSA) guidance.

8. Costs and benefits

8.1 A full Financial Impact Assessment was prepared to accompany the NHS Redress (Wales) Measure 2008. This has now been updated and is attached at Annex 2. The costs and benefits of the options set out above are as follows:

Option 1 – Do nothing

8.2 Allowing the current arrangements to carry on would risk the continuation of duplication of effort, more investigations of the same issues and poor use of existing resources and could not be said to bring any benefits. There is even recent evidence to hand to show that cases are being investigated locally, then followed by an independent review, then by referral to the Ombudsman, all of which are costly processes which could be circumvented in many cases by a proper and thorough investigation at the outset. To allow the continuation of the pattern of current claims, with associated legal costs, would be to ignore both the potential for savings in relation to legal costs that setting out these arrangements in legislation could bring, and also the possibility that patients' needs in some cases could be better met by alternative arrangements.

Option 2 – issue guidance, falling short of legislation

8.3 The benefits of issuing guidance are of some value but limited, in that guidance can be disregarded and may not provide a focus for consistent improvements. In terms of costs, these are related to the missed opportunities outlined in Option 1.

Option 3 – set out the arrangements in new legislation

8.4 The Assembly Government is of the view that investing in revised arrangements for more effective and proportionate investigation of concerns will in time prove to be good value for money and will result in significant benefits both to patients and to the health service. The Minister for Health and Social Services has identified just over £2.5 million per annum from 2011/12 to meet the costs of these new arrangements. This includes additional funding for an expected increase in the number of claims settled.

Impact on other sectors

8.6 *Small business:* In terms of the impact on legal firms involved in medical negligence work, this legislation is unlikely to impose any additional costs. Lower value claims make up a significant part of the clinical negligence solicitors' workload, although at present there is no consistent fee structure. There is also nothing to prevent a non-specialist becoming involved in a clinical negligence case at present, although in practice the majority of claims are dealt with by specialist firms because of Legal Services Commission rules on access to legal aid. Under the new arrangements, where the vast majority of claims under £25,000 will be handled, "expert" firms will still attract work, perhaps even more than now, although it is intended that specialist solicitors will work for staged, fixed fees. Some work has already been undertaken on such a fee structure by the Legal Advice

Working Group (which included claimant solicitor representatives) which was established as part of the “Putting Things Right” Project. We can therefore conclude that there could be some loss of income to non-specialist legal firms which will not be able to give legal advice under the Regulations, but that it is unlikely to substantially affect the specialist firms. However, this would have to be viewed against the overall expected gain to the public purse in terms of early settlement and the ability to divert any money saved towards settling more cases or even to frontline services.

8.7 *Local government/voluntary sector*: We do not anticipate that the Regulations will impact significantly on local government or the voluntary sector.

Duties

8.8 An equality impact screening assessment has been carried out and this is attached at Annex 3.

9. Competition Assessment

9.1 We do not consider it necessary to undertake a competition assessment for these Regulations since they will not affect the business sector in any significant way. The filter questions are shown at Annex 4.

10. Post implementation review

10.1 The Regulations provide for two types of monitoring and learning – monitoring the process, which will be done via statistical returns and annual reports; and learning from concerns, which requires organisations to demonstrate that they have proactively used the outcome of investigations to learn lessons and built them into service improvements. The Directorate General will issue guidance to the NHS in terms of what it will expect to see by way of information.

ANNEX 1

INFORMAL EXPLANATORY NOTES

Introduction

1. These informal notes have been prepared on behalf of the Minister for Health and Social Services by the Welsh Assembly Government, Health and Social Services Directorate General. They provide readers with an explanation of the effect and intention of the above draft Regulations which the Minister intends laying in the near future. The notes need to be read in conjunction with the draft Regulations. They are not, and are not meant to be, a comprehensive description of the Regulations.

2. Part 10 dealing with transitional and consequential provisions and revocations, and the Schedules are not generally covered below as they are purely technical in nature. The only exception to this is a summary of how the transitional provisions will work.

Summary

3. In summary, these Regulations make new arrangements for the notification and consideration of and response to concerns notified by persons in respect of services provided by or under arrangements with the National Health Service in Wales. A concern is defined as a complaint (which includes an expression of dissatisfaction), any issue arising from a patient safety incident and, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation.

4. NHS bodies in Wales, primary care providers in Wales and independent providers in Wales must all follow the procedures for receiving, handling and investigating concerns set out in Parts 3, 4 and 5 of the Regulations.

5. In addition, NHS bodies in Wales must, when they receive notification of a concern in accordance with these regulations, consider whether there may a qualifying liability in tort in respect of qualifying services. If they are of the view that there may be such a liability ie that there is the possibility that the person notifying the concern may have received negligent treatment, they must in accordance with the provisions of Part 6 of the Regulations investigate whether or not there is a qualifying liability in tort for which an offer of redress may be made. Primary care providers do not have to consider redress as an undertaking was given that they would not be included in the new arrangements straight away as they are indemnified by medical defence organisations and there are different considerations involved in making them the subject of the redress arrangements. Similarly, independent providers do not have to consider redress as they are not covered by NHS indemnity and rely upon the medical defence organisations for indemnity.

6. The Regulations provide for an offer of redress to comprise of the making of an offer of compensation and/or offers of remedial treatment, an explanation of what went wrong, an apology and the making of an action plan to prevent similar incidents occurring again. The Regulations also provide, if an NHS body is of the opinion that there is or there may be a qualifying liability in tort in respect of qualifying services, for a patient to receive free legal advice from a solicitor who specialises in clinical negligence claims in order to ensure that he or she is properly informed in relation to any offer that is made or refusal to make an offer if, on full investigation, it is determined that there is no qualifying liability.

7. Part 7 of the Regulations deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with NHS providers **outside** of Wales for the provision of services. Further detail of the policy is set out below but, in essence, NHS bodies in England are under an obligation in the Regulations to consider whether or not there is or there may be a qualifying liability in respect of services that they have provided under an arrangement with a Welsh NHS body. If they are of the view that there is such a qualifying liability, they are placed under an obligation in the Regulations to refer the case to the relevant Welsh NHS body together with the supporting information that they are required by the Regulations to provide. The Welsh NHS body will then determine whether or not there is a qualifying liability for which an offer of redress should be made.

8. Similarly, the Regulations place an obligation on Welsh NHS bodies to consider any notification of treatment that may qualify a patient for redress that is received from a NHS provider in Scotland or Northern Ireland with whom they have entered into an arrangement for the provision of services. The Welsh NHS body will then have to determine whether or not there is a qualifying liability for which an offer of redress should be made. Due to differences in our legal powers, in respect of bodies in Scotland and Northern Ireland, the Regulations do not place any obligations on such Scottish or Northern Irish providers to consider whether or not there may be a qualifying liability in respect of services that they have provided and to provide information to the Welsh NHS body. Instead, the intention is to place such obligations on Scottish and Northern Irish bodies in commissioning contracts.

PART 1 – GENERAL (REGULATIONS 1 – 3)

Regulation 2 defines words and phrases that are used throughout the body of the regulations including key definitions such as “concern”; “primary care provider”; “Welsh NHS body”; “responsible body”; “qualifying services” and “qualifying liability”.

Regulation 3 sets out the general principles that must be followed when handling and investigating concerns under the Regulations. This is an

important section as this makes clear what people can expect from the process and how they will be treated. It also provides for a person within the organisation that is the subject of a concern to act as contact throughout the handling of a concern (regulation 3(f)(iii)).

PART 2 – DUTY TO MAKE ARRANGEMENTS FOR THE HANDLING AND INVESTIGATION OF CONCERNS (REGULATIONS 4 – 9)

Regulation 4 places a duty on responsible bodies to make arrangements for the effective handling and investigation of concerns.

Regulation 5 says that information in a variety of formats will have to be provided free of charge about the arrangements for dealing with concerns. This is to ensure that there is equitable access to the arrangements and that people are not deterred from coming forward. The details will be covered in guidance but the intention is that the needs and requirements of various sectors of the community should be provided for and reflected in information about the arrangements (e.g. the needs of older people; children and young people; people with mental health problems; people with learning disability; people with physical disability including sensory impairment; the BME community; the LBG community). We will also make clear in guidance that primary care practitioners will be provided with relevant leaflets and materials via their Local Health Boards and will not have to produce their own

Regulation 6 stipulates that responsible bodies must designate someone to maintain a strategic overview of the arrangements to ensure that they are being operated properly. For Welsh NHS bodies (Local Health Boards and NHS Trusts) this will be a non-officer or non-executive member.

Regulation 7 provides that a responsible body must have identified a senior person in an executive role, in the regulations referred to as a “responsible officer”, to have responsibility for the effective day to day operation of the arrangements to ensure concerns are dealt with in an integrated manner.

Regulation 8 requires the appointment of a senior investigation manager who will oversee the handling and consideration of concerns.

Regulation 9 provides that a responsible body must ensure that staff involved in the handling and investigation of concerns are appropriately trained.

PART 3 – NATURE AND SCOPE OF THE ARRANGEMENTS FOR HANDLING CONCERNS (REGULATIONS 10 – 16)

Regulation 10 provides that a responsible body must handle concerns in accordance with the arrangements for handling concerns set out in the Regulations. Regulation 10 is subject to the provisions of regulation 14 which sets out which matters and concerns are excluded from consideration under the Regulations.

Regulation 11 stipulates that a concern may be notified in writing, electronically or verbally.

Regulation 12 sets out who can notify a concern. This includes patients who are receiving or have received services from a responsible body (or people acting on their behalf); a member of staff of a responsible body and a non officer member, non executive director or partner in a responsible body. The Regulation goes on to provide that children and young people may raise concerns on their own behalf and that they must be provided with assistance to do so if they require it. A representative, normally a parent, may still notify a concern on behalf of their child if there are reasonable grounds for the parent to notify the concern rather than the child. Normally a parent will notify a concern where a child lacks the understanding to be able to make an effective complaint him or herself (even with the assistance of trained advocates). Members of staff can also raise concerns about incidents. However, it is important to point out that this is not the same as a "whistle blowing" policy, although the arrangements may well have some overlap. This will be clarified further in guidance, but the general position is that if a member of staff reports an incident and initial investigations reveal that there may be a conduct issue relating to another member of staff then the relevant HR policies may then be triggered. Unless regulation 12(8) applies, *regulation 12(7)* requires the NHS body to advise the patient or their representative when a concern has been reported by a member of staff and if the investigation reveals that there has been moderate or severe harm or death. Regulation 12(8) applies where, in the opinion of the responsible body, it would not be in the interests of the patient to be informed of or involved in the investigation of the concern. It is envisaged that regulation 12(8) would apply where it is considered that involving a patient would cause harm to his or her mental or physical health.

Regulation 13 sets out that a concern can be notified to a Welsh NHS body about any matter connected with the exercise of its functions; a primary care provider in Wales about the provision of services by it under a contract or arrangements with a Welsh NHS body; or to an independent provider in Wales about the provision of services by it under arrangements with a Welsh NHS body. Provided that the requirements of regulation 18 are met, it also provides that a Local Health Board can investigate a concern about a primary care provider in Wales. However, a Local Health Board cannot make any determination in respect of the liability in tort of a primary care provider and this is set out in *Regulation 23(2).* This is included as the redress arrangements do not apply to primary care providers.

Regulation 14 provides for those matters which are excluded from consideration under the arrangements. In particular, concerns relating to matters which are or which become the subject of legal proceedings will not be dealt with under the arrangements. This is because in those cases, the patient has chosen to take a different route for the resolution of their concern. Also, *Regulation 14(1)(j)* excludes concerns about individual patient funding requests, as these will be dealt with by a different process.

Regulation 15 sets out the time limits which apply for the notification of concerns under the Regulations. A general 12 month time limit will apply for raising concerns. The 12 month time limit will run from the date of the incident in respect of which a concern is being notified, or, if later, 12 months from the date on which the matter which is the subject of the concern came to the attention of the person notifying the concern. However, regulation 15(2) provides that the 12 month time limit will not apply if the responsible body believes that the person notifying the concern had good reason for not notifying the incident sooner and, notwithstanding the delay, it is still possible to investigate the concern effectively. Regulation 15(3) provides that a concern may not be notified three or more years from the date of the incident complained about or three or more years from the date that the patient became aware of the matter which is the subject of the concern. This “endstop” has been inserted to make the absolute final time limit for notifying a concern consistent with the limitation period for the majority of clinical negligence claims.

Regulation 16 allows for the withdrawal of concerns at any time by the person who notified the concern, but provides that the responsible body may continue to investigate, if it felt that it was necessary to do so.

PART 4 – CONCERNS WHICH INVOLVE OTHER RESPONSIBLE BODIES (REGULATIONS 17 – 21)

Regulation 17 sets out how a concern should be handled if it covers more than one responsible body – i.e. Welsh NHS bodies, primary care providers in Wales and independent providers in Wales.

Regulations 18, 19, 20 and 21 cover situations where a concern about a primary care provider is notified to the Local Health Board with whom the primary care provider, who is the subject of the concern, has entered into a contract or arrangement. A concern may be notified to the Local Health Board by the person who is notifying a concern or the primary care provider who is the subject of the concern. These Regulations require a Local Health Board that receives notification of a concern about a primary care provider to consider whether it is appropriate for it to investigate the concern, or whether the matter should be investigated by the primary care provider. It also makes clear that if the primary care provider has already responded to a concern, the Local Health Board must not consider the matter.

PART 5 – HANDLING AND INVESTIGATION OF CONCERNS (REGULATIONS 22 – 24)

Regulation 22 sets out what must happen before the investigation begins, in terms of notification of receipt of the concern, the offer of a discussion about how the concern will be handled and what support might be needed.

Regulation 23 provides that a responsible body must investigate the matters raised by a concern in the manner which appears to that body to be the most appropriate. It must have particular regard to the matters raised in regulation

23(1) such as consideration of initial assessment of a concern, whether clinical advice is required, whether mediation or facilitation might be employed to help resolve the concern and the consideration of the likelihood of any qualifying liability. Regulation 23(1)(i) provides that where a Welsh NHS body receives notification of a concern which includes an allegation that harm has, or may have been caused it must consider the likelihood of any qualifying liability; the duty to consider redress in accordance with the provisions of regulation 25; and, where appropriate, consideration of the additional requirements set out in Part 6. Primary care providers and independent providers do not consider the matters in regulation 23(1)(i) as the "redress" element of the Regulations does not apply to them. *Regulation 23(2)* makes clear that if a Local Health Board is investigating a concern about a primary care provider, it will not consider qualifying liability and the associated redress provisions in such a case.

Regulation 24 sets out what must be included in the response to an investigation of a concern under regulation 23 and the timescales which apply. Regulation 24 does not apply where a Welsh NHS body believes that there is or there may be a qualifying liability. In those circumstances a Welsh NHS body must make an interim report about the concern in accordance with regulation 26. The content of the interim report is set out at *Regulation 26.*

PART 6 – REDRESS (REGULATIONS 25 – 33)

Regulation 25 sets out a general duty on Welsh NHS bodies to determine whether or not to make an offer of redress to the patient if an investigation in accordance with Regulation 23 reveals that a qualifying liability exists or may exist. Regulation 25(2) provides that an offer of redress may be made by a Welsh NHS body where it is established, in accordance with the Regulations, that a qualifying liability exists.

Regulation 26 sets out what must be contained in an interim report where the initial investigation under regulation 23 reveals that there is or there may be a qualifying liability, and the timescales which apply.

Regulation 27 provides for the forms that redress can take under the Regulations.

Regulation 28 sets out that redress will not be available if the matter is or has been the subject of civil proceedings.

Regulation 29 sets a global limit of £25,000 for any award of financial compensation made under the redress arrangements. This encompasses general and special damages and is a reasonable limit that would encompass the vast majority of the lower value claims that are currently settled by NHS bodies. This limit should have the effect of excluding complex fatal accident cases with significant claims for loss of earnings, dependency etc., which was a matter of some concern to respondents to the consultation.

If it becomes apparent that the amount of damages will exceed this amount redress, in accordance with the Regulations, must not be offered. However,

regulation 29(3) provides that where the financial limit will be exceeded a Welsh NHS body may give consideration to the making of an offer of settlement outside of the redress arrangements under the Regulations.

Regulation 30 makes provision allowing for the limitation period for bringing a civil claim for clinical negligence to be suspended whilst an application for redress is being considered. Limitation is suspended from the date on which a concern is first received by a Welsh NHS body and the regulations make provision for the patient and his or her legal representative to have time to consider any offer of redress before the limitation period will start to run again.
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Regulation 31 provides for the findings of the investigation in relation to redress to be recorded in an investigation report.

Regulation 32 provides that where a Welsh NHS body has determined that a qualifying liability exists or may exist it must ensure that legal advice is available in accordance with the provisions of regulation 32. It also provides that where medical experts need to be instructed they are instructed jointly by the Welsh NHS body and the person who notified the concern. Regulation 32(2) provides that legal advice may only be sought from firms of solicitors that can demonstrate they have an expertise in clinical negligence matters. Expertise can be demonstrated if a firm has at least one partner or employee who is a member of the Law Society Clinical Negligence Panel or the Action Against Medical Accidents Clinical Negligence Panel. Only legal advisers with recognised expertise in the field of clinical negligence will be able to participate as this is felt to be the best use of public money and will also afford the best service to patients. The cost of such legal advice and clinical experts will be borne by the Welsh NHS body and not the patient. Regulation 32(3) sets out the points in the process when legal advice must be made available under the Regulations. It is intended that specialist solicitors will work for staged, fixed fees. Some work has already been undertaken on such a fee structure by the Legal Advice Working Group (which included claimant solicitor representatives, representatives from Welsh Health Legal Services and the patient safety charity – Action Against Medical Accidents) which was established as part of the "Putting Things Right" Project. The fee structure will be finalised before the Regulations come into force.

Regulation 33 prescribes the time limits that apply to the making of offers of redress, the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 33(e) provides that any offer of settlement must be by way of formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates.

PART 7 – REQUIREMENT FOR PERSONS AND BODIES, OTHER THAN WELSH NHS BODIES, TO CONSIDER REDRESS AND PROCEDURE TO BE FOLLOWED BY A WELSH NHS BODY WHEN IT RECEIVES NOTIFICATION OF A CONCERN IN ACCORDANCE WITH THE PROVISIONS OF THIS PART (REGULATIONS 34 – 48)

Part 7 of the Regulations deals with how redress is to be provided where Welsh NHS bodies enter into arrangements with NHS providers **outside** of Wales for the provision of services. Independent providers and primary care providers are excluded from the scope of the arrangements under Part 7.

Regulation 34 sets out the definitions of terms used in this part of the Regulations. It includes definitions of the terms "English NHS body", "Scottish NHS body" and "Northern Irish NHS body".

It should be noted that care is not routinely commissioned from NHS bodies in Scotland and Northern Ireland and so it is anticipated that there will not be many instances where a Welsh NHS body will be required to consider redress in respect of a concern that has been notified to it by a Scottish or a Northern Irish NHS body. However arrangements are routinely entered into with English NHS bodies for the provision of services and so the likelihood of the provisions being engaged is greater. To allow for further discussions on the practical application of the arrangements in England, this Part of the Regulations will commence later, on 1 October 2011.

Regulation 35 provides that where an English NHS body receives notification of a concern under a relevant complaints procedure in respect of a service which it has provided, or arranged for the provision of, under an arrangement with a Welsh NHS body it **must** consider whether or not the concern is one to which the redress arrangements could apply. A relevant complaints procedure would, in relation to English bodies, currently be the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 ("the 2009 Regulations").

Regulation 36(1) provides that if an English NHS body concludes that a qualifying liability which might give rise to a successful application for redress exists or may exist, it must take the steps outlined in regulation 36(2). .

Regulation 36(2) provides that the English NHS body must notify the Welsh NHS body with which it has entered into a contract if it is of the view that a qualifying liability exists or may exist and, after obtaining any necessary consents, provide the Welsh NHS body with:

- Its response to the concern/complaint that it provided to the patient in accordance with the complaints procedure which it is bound to follow. Currently the procedure set out in the 2009 Regulations ;
- A copy of relevant medical records;
- A copy of any expert opinion obtained during the complaints investigation;

- A written account of why the provider believes there is or may be a qualifying liability;
- The date the concern was received; and
- Any other information and assistance that the Welsh NHS body may require.

Regulation 37 provides that the Welsh NHS body must then acknowledge receipt of the information; advise the person who notified the concern to the English NHS body that the concern has been passed to it to consider whether or not there is a qualifying liability in tort and must determine, in accordance with the provisions of Part 7, whether or not an offer of redress should be made to the patient.

This is not covered in the Regulations as it is not appropriate for it to do so. However, in accordance with the law of England and Wales, any successful application for redress will be settled on the basis of the English provider's liability in tort. It is considered that this is appropriate as the law of tort is the same in England and Wales. This policy was agreed with the Department of Health when the NHS Redress Bill was progressing through Parliament and the NHS Redress Act 2006, from which we ultimately derive our legal powers (via a an order converting the framework powers in that Act into legislative competence which was used as the basis for drafting the NHS Redress (Wales) Measure 2008) was drafted on that basis.

This would mean that the waiver that a patient is required to sign in accordance with regulation 48(e) would be in respect of the provider body's liability in tort (ie the English NHS body's liability).

It is anticipated that the Welsh NHS body would pay any settlement costs up front and the legal fees and fees for clinical reports as it is responsible for running the redress arrangement. However, as the claim is being settled on the basis of the English NHS body's liability in tort towards the patient, it is intended to require LHBs and Trusts in Wales to ensure that any commissioning contract with English NHS provider bodies contains provision allowing for the recovery of such costs. This includes the cost of legal fees and any associated clinical fees where an investigation by a Welsh NHS body reveals that there is no qualifying liability in tort. This arrangement was outlined in the technical consultation which ran in September of last year and discussions have already started with the Department of Health.

Regulation 38 prescribes the action that a Welsh NHS body must take if it receives notification from a Scottish NHS body or a Northern Irish NHS body that there is, or there may be, a qualifying liability in tort in respect of services which it has provided, or arranged for the provision of, under an arrangement with the Welsh NHS body. The Welsh NHS body must acknowledge receipt of the notification, advise the person who notified the concern to the provider that the concern has been passed to it to consider whether or not there is a qualifying liability in tort and must determine in accordance with the provisions of Part 7 whether or not an offer of redress should be made to the patient.

No obligations are placed on Scottish NHS bodies or Northern Irish NHS bodies under the Regulations because of differences in our legal powers in respect of bodies in these countries. Therefore, the Regulations do not place obligations on NHS bodies in those countries who enter into arrangements for the provision of services with Welsh NHS bodies to consider whether there is a qualifying liability in tort and to notify Welsh NHS bodies.

However, it is the policy intention to require Local Health Boards and NHS Trusts in Wales, if they enter into commissioning agreements with Scottish NHS bodies or Northern Irish NHS bodies for the provision of services, to insert a provision in the commissioning contract which requires the provider to consider, if it receives a complaint about such services which it has provided or arranged for the provision of under the terms of the complaints procedure that it is required to operate, whether there is or there may be a qualifying liability in tort. If the provider is of the view that there is or there may be such a liability then, in accordance with the terms of the commissioning contract, it must refer the case to the Welsh NHS body to deal with in accordance with the provisions in regulation 38 and the rest of Part 7. It is also intended to place an obligation on Scottish and Northern Irish providers in commissioning contracts to provide the Welsh NHS body with the same information that an English or a Welsh provider is required to send under regulation 36.

Any successful application for redress in respect of the services provided by NHS bodies in Scotland or Northern Ireland would be made on the basis of the Welsh NHS body's own non-delegable duty of care to the Welsh NHS patients who had been sent to Scotland or Northern Ireland for treatment. This means that the compensation and associated legal costs would be met by the Welsh body as the waiver that a patient would be required to sign in accordance with regulation 48(e) would be in respect of the Welsh body's liability towards the patient and not that of the provider body.

Regulation 39 places a duty on Welsh NHS bodies to offer to meet with the person who notified the concern and then to conduct an investigation. If an English NHS body makes a notification of a concern to a Welsh NHS body in accordance with regulation 36, regulation 39(2) provides that the two bodies must co-operate, in a way which satisfies the requirements of Part 7 of the Regulations, to determine whether or not a qualifying liability exists and, if it is determined that a qualifying liability does exist, to make an offer of redress to the patient.

Regulation 40 sets out the content of an interim report to a concern notified in accordance with the provisions of this Part where, following an investigation under regulation 39, a Welsh NHS body is of the opinion that there is or there may be a qualifying liability in tort. It provides that the Welsh NHS body must produce an interim report, normally within 50 working days from the date on which it received notification of the concern. This is longer than the general requirements set out at Regulation 26 because of the possible need to obtain further information from the body that actually provided the service in question.

Regulation 41 sets out what will happen if the Welsh NHS body concludes, following the investigation undertaken in accordance with regulation 39 that there is no qualifying liability on the part of the provider person or body.

Regulation 42 provides for the forms that redress can take under Part 7 of the Regulations, which are the same as set out in *Regulation 27*.

Regulation 43 makes clear that redress will not be available if the matter is or has been the subject of civil proceedings and if civil proceedings are issued during the course of a Welsh NHS body's consideration of redress, the Welsh NHS body's consideration of redress must stop and the Welsh NHS body must notify the person who notified the concern and the English NHS body, Scottish NHS body or Northern Irish NHS body.

Regulation 44 is similar to *Regulation 29* and sets a global limit of £25,000 for the financial element of redress. This encompasses general and special damages. Regulation 44(2) provides that if on investigation it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Provisions of Part 7 must not be offered. The regulation provides that the compensation that will be awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue a compensation tariff. If, in the case of a matter referred from an NHS body in England, Scotland or Northern Ireland the amount is likely to exceed the limit shown, then the Welsh NHS body will not proceed to consider an offer outside the Regulations. Guidance will cover the action that Welsh NHS bodies should consider taking should such an occurrence arise.

Regulation 45 is similar to *Regulation 30.* It deals with the suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 7 of the Regulations. Regulation 45(2)(a) provides that the relevant limitation period will be suspended from the date on which the initial concern was received by the English NHS body, Scottish NHS body or Northern Irish NHS body.

Regulation 46 is the same as *Regulation 31* and provides for the findings of the investigation in relation to redress to be recorded in an investigation report.

Regulation 47 is the same as *Regulation 32* and provides for the instruction of legal advisers at certain points in the process, and medical experts where appropriate. There is one difference, regulation 47(4) provides that the Welsh NHS body must bear the cost of instructing legal and medical experts but recognises that this is subject to any rights that a Welsh NHS body will have to recover such monies from the English NHS body. As stated above, it is the intention that the commissioning contract between the Welsh NHS body and the English NHS body will detail the arrangements for the recovery of monies.

Regulation 48 prescribes the time limits that apply to the making of offers of redress, the communication of decisions not to make offers of redress; the time limits for considering offers and refusals to make offers and extensions to such time limits. Regulation 48(e) provides that any offer of settlement must be by

way of formal agreement which must include a waiver of any right to bring civil proceedings in respect of the qualifying liability to which the settlement relates.

PART 8 – LEARNING FROM CONCERNS (REGULATION 49)

Regulation 49 sets out that responsible bodies must ensure that it has in place processes to review the outcome of any concern that has been subject to an investigation in accordance with the Regulations and any deficiencies identified in investigations are promulgated throughout that body in order to learn lessons, avoid such deficiencies occurring again and to improve services.

PART 9 – MONITORING THE PROCESS (REGULATIONS 50 – 51)

Regulation 50 provides for the collection of information about the number of concerns handled and investigated and the subject matter, as well as those considered under the redress arrangements.

Regulation 51 requires an annual report to be produced.

PART 10 – TRANSITIONAL AND CONSEQUENTIAL PROVISIONS AND REVOCATIONS

Regulation 52(2) provides that where a complaint has been made under the former complaints provisions (as defined in regulation 52(1)) before 1 April 2011 that complaint may continue to be investigated in accordance with those provisions provided that it is not excluded from consideration by any provision within the former complaints provisions. Similarly, regulation 52(3) provides that where a person has requested an independent review in accordance with the former complaints provisions, the case must be handled in accordance with the former complaints provisions, including the setting up of a panel if appropriate.

Regulation 52(4) provides that save in respect of a complaint that would be subject to the arrangements in Part 7 of the Regulations, where a complaint, the subject matter of which occurred before the 1 April 2011, has not been the subject of a previous NHS complaint and is not excluded from consideration under any provision of these Regulations, it may be considered in accordance with the terms of these Regulations.

Regulation 52(5) provides expressly that complaints about services provided by English NHS bodies, Scottish NHS bodies or Northern Irish NHS bodies made before 1 October 2011 will not be considered under Part 7 of these Regulations. The reason for this is to give time for the relevant contractual arrangements and guidance to be put in place.

ANNEX 2

DRAFT NATIONAL HEALTH SERVICE (CONCERNS, COMPLAINTS AND REDRESS ARRANGEMENTS REGULATIONS) (WALES) 2011
FINANCIAL IMPACT ASSESSMENT – JANUARY 2011

Introduction and background

1. The Health and Social Services Directorate General of the Welsh Assembly Government has prepared this document to accompany the laying of the above Regulations.

2. A similar Financial Impact Assessment was prepared for the passage of the NHS Redress (Wales) Measure 2008. At that time, we were of the view that potential additional costs arising from the introduction of new arrangements would range from £2.4m to £3.6m. With the reorganisation of the NHS in Wales, we have now been able to considerably refine the estimates. In particular we are now of the view that we can revise downwards the estimate required for investment in staffing, given that the opportunities for staff restructuring and redeployment that the reform programme affords. Financial provision of £2.514m has been made for 2011/12 to embed the new arrangements and £2.388m for 2012/13. A budget of £1.8m has been available in 2010/11 for development and preparatory work. In light of the above we are of the view that the programme can be delivered within these amounts.

3. A table showing the potential financial implications of implementing the revised arrangements in 2011/12 and 2012/13 is shown below:

Item	Estimated costs (£000) 2011/12	Estimated costs (£000) 2012/13
1. Development of staff skills and training including LHB staff, primary care practice managers, CHC advocacy staff	383	270
2. Guidance and information materials, leaflets, etc	50	10
3. Update of NHS information software for data collection	80	0
4. Independent Review (IR) – handling of residual cases within 6-8 months (around 60 cases of which around 8 might go to panel. Includes lay reviewer and secretariat costs – same staff to possibly be retained to administer requests for clinical and legal advice (say 1 x Band 6 and 1.5 x Band 4)	95	72
5. Independent Review costs already in the system which can be recouped and added back	(141)	(164)
6. Independent Review staff to transfer to LHBs (say 2 x Band 6, 1.5 Band 4 and 1 Band 2)	118	118
7. Impact on Ombudsman's investigations	335	335
8. Impact on Welsh Health Legal Services	60	60
9. Advocacy and legal advice support for CHCs	240	240
10. Alternative dispute resolution (mediation and facilitation (£20k per organisation reducing to £10k after one year))	200	100
11. Remedial treatment	350	350
12. Damages based on worse case "averages" option	844	844
13. Legal advice costs (with the introduction of a fixed fee framework)	No additional costs	No additional costs
14. Expert clinical advice	100	100
Total	**2,714***	**2,335**

*Pressure shown to be managed in year as other estimates are further refined.

4. The following paragraphs provide a background to and an explanation of the above estimates, shown in the same order as they are in the table.

Predicted costs and potential savings

Item 1: Development of staff skills and training

5. The Regulations provide for a single investigation process to be put in place for complaints, claims and patient safety incidents. This will require staffing levels and skills suitable to both conduct and oversee robust and appropriate investigations as well as to be able to consider issues such as liability and settlement of claims in appropriate cases. There is already a considerable pool of resources in the NHS dealing with work of this nature. The recent NHS reorganisation has presented an ideal opportunity for the new organisations to put structures in place to support best practice in the handling and investigation of concerns and interim guidance was issued in October 2009 to support this.

6. Some work was done in the autumn of 2007 to ascertain the skill mix and resource devoted to the resolution of complaints, claims and incidents, which produced useful results and which enabled us to estimate the further investment in skills and training that may be required.

7. It was estimated at that time that between £2.4m and £3m per annum was being spent on the direct employment of staff involved in the handling of concerns. Additionally, there remains the considerable and uncalculated "hidden" cost of operational and clinical staff time spent contributing to investigations.

8. The work identified a need for at least one senior and highly skilled lead officer in each organisation to oversee a suitable structure as well as supplementing existing staff both in sufficient numbers and competency so that they are able to take on additional work across the range. Since those estimates were done, the NHS reorganisation has been implemented, meaning that there is now the opportunity to look across a wider range of staff to identify and develop people with suitable skills.

9. The Regulations also provide that Local Health Boards (LHBs) may investigate formal complaints and issues concerning GPs and other primary care practitioners, if requested to do so. It is as yet unclear how many complaints would fall to be investigated in this way and what additional costs would arise for the LHB teams. However, LHBs will be advised to keep under review their skills, capacity and staff structure to ensure that the capability is developed in this regard. In addition, primary care practice managers are being included in the LHBs' training programmes in relation to investigation and other skills.

10. It is envisaged that additional training for frontline staff in disclosure and investigation would be required over the first two years to encourage a proactive culture in dealing with things that go wrong. This will include specific training to increase the number of individuals who could conduct Root Cause Analysis investigations. A previous programme, funded

centrally through the Department's agreement with the NPSA, provided training to all NHS organisations in Wales. A training needs analysis exercise completed in 2010 identified that with an integrated investigation process, the need to extend such training to a much wider group of staff. To ensure consistency a further all-Wales programme has been commissioned with the NPSA to deliver this. The programme has already started with training being delivered in organisations from January 2011.

11. Each organisation will also receive funding (part funding has already been made) for the appointment of facilitators within each of the organisations with the specific role of delivering training more generally on the new arrangements. The Directorate General is developing a suite of materials including an e-learning package; presentations and handouts and video resources to support the delivery of training across the organisations.

Item 2: Guidance and information materials

12. The Assembly Government intends to produce implementation advice for the service, in the form of a e-manual, potentially complemented by a series of road show events to publicise the new arrangements.

13. Leaflets are also being produced to be made available to the public at selected locations, in a number of formats and languages.

Item 3: Update of NHS information software for data collection

14. There is a potential need to invest in some updating of software in the NHS organisations to allow for consistent data collection and reporting across claims, complaints and patient safety incidents, as there is some evidence that certain organisations are further forward than others. Officials are currently looking into this in more detail to see whether this investment is essential or whether other arrangements can be put in place. A provisional figure is proposed to allow for the purchase of 16 new modules if necessary.

Items 4, 5 and 6: Independent Review

15. Independent Review (IR) currently forms the second stage of the complaints procedure and will be phased out under the new arrangements. It currently costs around £354,000 per annum which funds staff located at the NHS Business Services Centre, independent lay reviewers' fees and expenses, training and development and panel costs. Additionally around £100,000 per annum is paid by NHS organisations for clinical advice to support the IR process.

16. In the autumn of 2007 questionnaires were used to gather views on IR process from the Welsh NHS and members of the public who have used the process. The feedback was mixed. Many suggested the process raised complainants' expectations, but was then unable to deliver the outcome

they wanted while others felt IR gave organisations a useful second chance to put things right.

17. In its final report the Investigation and Process Working Group recommended that Independent Review be removed as a second stage of the complaints process. People who remain unhappy following local attempts at resolving their concerns would be able to ask the Ombudsman to investigate. This recommendation has been accepted. It is also consistent with the recent recommendations made by a working group led by the Public Services Ombudsman for Wales, which made recommendations for a single stage process across the whole of the public sector. The First Minister has accepted those recommendations.

18. The Regulations provide for the IR process to be brought to an end. Abolishing the IR process would potentially release £454,000 per annum (including clinical advice costs). However, not all of this funding will be directly recouped. Some current staff will be redeployed within the wider structure for the handling of concerns, thus decreasing this saving, and a core will need to be retained for the administration of requests from NHS bodies for independent clinical and legal advice. In the first year of the new arrangements, there will also be a need for cases which were started before 1 April 2011 to be completed. The table shows the estimated costs associated with phasing out the independent review stage and of redeploying staff to other duties within the new arrangements, together with the residual saving that can be expected.

Item 7: Impact on Ombudsman's investigations

19. New, more accessible and proactive arrangements are bound to increase the number of investigations to be conducted locally. Whilst the aim is to handle the vast majority of these successfully at local level, we would anticipate an increase in the number of cases going to the Ombudsman, particularly if the IR process is abolished. In Scotland, IR was abolished in 2005 and there was a 128% increase in cases going to the Ombudsman in 2005/06. The measures introduced in Scotland that year in the revised NHS complaints procedure sought to make it easier to use and emphasised the message: "it is OK to complain". If IR were to be abolished in Wales and, as expected, the number of concerns received were to increase, cases received by the Public Services Ombudsman for Wales could increase by a similar amount, for example, from 191 to 364 cases (based on 2006/07 figures).

20. Further work was done with the Public Services Ombudsman for Wales's office on the potential impact on his workload of any change in arrangements. It was agreed that there would be an increase in cases going to the Ombudsman, based on the numbers that already go, and the inevitable increase in cases overall, if the NHS saw more coming forward under new arrangements. In mitigation if more cases were to be successfully resolved locally, then this should prevent a certain number having to be escalated to the Ombudsman. A very broad estimate from the

Ombudsman was that he might see an additional 100 cases annually, and the table shows the latest estimates from his office on the amount of additional funding he will require to undertake this work.

Item 8: Impact on Welsh Health Legal Services

21. NHS organisations are likely to increase their demand for advice from Welsh Health Legal Services (WHLS) during the implementation of the new arrangements. WHLS has employed a dedicated resource whose role it is to both provide training on liability, quantum, etc to NHS investigation staff, and to support the organisations with specific case-related queries. The table shows the cost of this resource which will be funded for the next few years until skills are sufficiently build up in the NHS organisations.

Item 9: Advocacy and legal advice support for CHCs in Wales

22. Community Health Councils in Wales are already providing an advocacy service for people wishing to make a complaint about the NHS in Wales. This will be enhanced to enable CHCs to support more people coming forward under the new arrangements. An additional £195k has already been allocated to CHCs in Wales for developments to the advocacy service. An additional £55k is estimated to cover specific support from a specialist service, to provide advice to advocates on potential issues of liability.

Item 10: Alternative dispute resolution (mediation and facilitation)

23. Both the Advocacy and Assistance Working Group and Legal Advice Working Group recommended the development of a more effective mediation service across Wales. There is already an Independent Complaints Facilitation Service available but there is relatively low uptake of the service, possibly because the service is funded by NHS organisations which may look for cheaper ways to resolve issues. Some investment may therefore be required to boost the use of this service to enable the resolution of issues earlier, saving time and money later on in the process. The table shows what we believe to be a realistic sum to pump prime the use of such services in the first year, reducing thereafter.

Item 11: Remedial treatment

24. It is difficult to estimate the costs of provision of remedial treatment, much of which may be provided in-house, however, we have made an estimate in the table to cover this element, and this will be kept under review.

Items 12 and 13: Legal costs and award of damages

25. We have based these estimates on a range of possible increases in the number of claims for £25,000 or less. The ranges shown stem from work originally done as part of the NHS Redress Bill.

Assumptions:

- In 2009/10, 163 cases settled for £25,000 or less at a total cost of £1,417,447
- Average damages per case = £8,696
- Average legal costs per case = £7,609 (approximately 12 per cent less than the average damages based on previous years' cases) x 163 = £1,240,267
- 15 per cent increase = additional 24 cases
- 43 per cent increase = additional 70 cases
- 60 per cent increase = additional 97 case
- Legal cost projections are based on the assumption that the vast majority of claims below £25k will in future go through the redress element of the new arrangements and so all possible cases are counted. The options are based on recommendations made by the Legal Advice Working Group of the Putting Things Right Project – the framework will be reviewed and finalised before the Regulations come into force.

DAMAGES FOR **ADDITIONAL** CASES			
	15 per cent increase in cases	43 per cent increase in cases	60 per cent increase in cases
If additional cases settle at average damages of £8,696	£208,704	£608,720	£843,512
If all additional cases settle at full £25k (unlikely)	£600,000	£1,750,000	£2,425,000
POTENTIAL LEGAL COSTS FOR **ALL** CASES BELOW £25K,			
	187 cases	233 cases	260 cases
No fee structure, using current average legal costs of £7,609	£1,422,888	£1,772,897	£1,978,340
Fixed fee for whole process of £3,500 for cases where there is agreement and £5,000 for cases where no agreement (equal split assumed)	£795,500 – representing a possible saving of £627,388 over the current average cost of fees	£991,000 – representing a possible saving of £781,897 over the current average cost of fees	£1,105,000 representing a possible saving of £873,340 over the current average cost of fees
Fixed fee for various stages in the process ranging from £1,500 to £3,000 to £5,000 (50/30/20 split assumed)	£494,000 – representing a possible saving of £928,888 over the current average cost of fees	£584,000 – representing a possible saving of £1,188,897 over the current average cost of fees	£689,000 – representing a possible saving of £1,289,340 over the current average cost of fees
Composite framework	Difficult to quantify but assume within the range of the fixed fee for various stages	Difficult to quantify but assume within the range of the fixed fee for various stages	Difficult to quantify but assume within the range of the fixed fee for various stages

<u>Explanation of the various fee options mentioned above</u>

- *No fee structure*

26. This assumes legal charges to be agreed along current rates, and so the current average legal cost is used.

- *Fixed fee for whole process*

27. Under the is option a fixed fee of £3,500 is proposed for fairly straightforward cases where there is concession of liability and £5,000 for cases where there may be no agreement regarding liability and which might be more complex for the legal advise to look at. The table assumes an equal split between the number of cases attracting £3,500 fee and £5,000 fee.

- *Fixed fee for various stages*

28. This option assumes a fixed fee for various stages. This means that legal advice could be as low as £1,500 in many cases but rise to £3,000 or more in others which are more complicated or where there is no agreement. The table assumes 50 per cent of cases could be settled within the £1,500 cost limit, 30 per cent within the £3,000 limit and 20 per cent within the £5,000 limit.

- *Composite framework*

29. This was recommended in the final report of the Legal Advice working group, and is based on having an hourly rate, capped at an upper limit, for straightforward cases, with fixed fees for other parts of the process. The recommendation was that those firms engaged in this work would be subject to audit during their involvement in the scheme and hourly rates and fixed fees to be reviewed on a regular basis. It is difficult to predict costs under such a framework but they are likely to be contained within the other estimates shown.

<u>Item 14: Clinical and Expert advice</u>

31. As indicated above under the IR process, there is already estimated to be £100,000 in the system for the commissioning of independent clinical advice as part of the independent review process. Legal costs also contain an element for expert advice. The cost of clinical advice can vary from as little as £450 for a report to over £1,000 depending on the complexity of the case and the speciality concerned. For the purposes of estimating costs, and based on a potential increases of 15%, 43% and 60% additional cases and an average of £700 per report, the cost of clinical advice for all cases below £25k could range from £131,000 (187 cases) to £182,000 (260 cases). Given the money already in the system, we would not propose making the whole amount available, but we have made provision for the additional £82,000, but made it up to £100,000 to accommodate the potential need for more clinical advice in cases overall, including those which do not proceed to the redress element of the arrangements

ANNEX 3

DETAILED EQUALITY IMPACT ASSESSMENT

Title

Putting Things Right – a better way of dealing with concerns about health services

Department

Health & Social Services Directorate General – Quality and Safety Division, Medical Directorate

Introduction

The Welsh Assembly Government wants to improve the way that health organisations deal with people's concerns about the health service. We want the health service in Wales to do as much as it can to put right mistakes and to learn lessons to stop them happening again. We feel that this can be done by improving the arrangements already in place to support all staff to be open with people when something has gone wrong and by developing further the skills and experience of staff who will investigate concerns. We also think that by giving health organisations the tools and techniques they need to carry out better investigations, more people will be satisfied with the result. The process should be easy to access and people should be able to get help and support to raise their concerns.

A consultation document was issued between 11 January and 2 April 2010 setting out the further changes we intend to make. A further technical consultation was carried out between 6 and 30 September on two specific issues.

The draft regulations were developed following involvement of a number of stakeholders, including:

- patient groups (i.e. Eiriol Mental Health Carmarthenshire; Swansea and Gwent Patient Involvement groups; Age Concern Cymru);
- staff interest organisations (i.e. RCN; BMA Wales; Medical Defence Union; Medical Protection Society);
- stakeholder groups (i.e. Community Health Council advocates; Sensory Impairment Working Group; Welsh Language Board).

Evidence sources and screening outcome

The screening assessment on pages 2–9 identified that a number of different groups of the various equality strands, as well as other identified groups, require careful consideration of their needs in any proposals developed.

We have identified that the way the NHS deals with/handles concerns needs to be improved so that:

- People find it easier to raise a concern.
- People have confidence in the process and trust it to deliver a fair outcome.
- Individual needs of those raising a concern are recognised at the outset i.e. preferred method of communication, language used and advocacy support.

Many of the issues raised in the assessment will be addressed in guidance to the NHS on the implementation of the new arrangements.

Health and Social Services
Directorate General
January 2011

SCREENING ASSESSMENT

PROPOSED POLICY:

Putting Things Right – How the NHS in Wales handles and investigates concerns.

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
Disability									
People with physical disability, including sensory	4, 9, 13, 17, 20, 25, 29			✓				✓	Inappropriate format of documentation; communication difficulties; lack of respect/dignity; finding it difficult to complain; recognise different levels of support; advocacy support is needed; need to capture communication needs on the patient record; need to provide variety of contact method other than the traditional ones; need for BSL and

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									other communication support, such as Sign Supported English, lip speaking, etc; staff training in deaf awareness; eye clinic liaison officers to assist people in resolving their concerns
People with learning difficulties	10, 11, 13		✓					✓	Advocacy support is needed; fear of being struck off for making a complaint; lack of accessible information; inappropriate format of documentation
Race									
BME Communities	1, 6, 13, 18			✓				✓	Language difficulties and problems with interpreters lacking confidence in translating medical terms; lack of awareness of how to make a complaint; assumption that lack of English means lack of capacity to

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									make decisions; advocacy support is needed; Inconsistent approach to interpreters and translators
Gypsy and Traveller Communities	12, 13, 16, 19		✓					✓	Improvement in communication needed; lack of confidence in professionals; lack of awareness of complaints process; advocacy support is needed; feeling of not being listened to; lack of respect by professionals in people's abilities to understand; suspicion and lack of trust; literacy problems; advocacy support needed to make a complaint; lack of cultural awareness and sensitivity of the needs
Migrant Workers	6, 11, 13, 14, 18			✓				✓	Assumption that lack of English means lack of capacity to make decisions;

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									lack of accessible information; flexibility in communication method; advocacy support is needed; translation service not routinely available; having to rely on family/friends to translate; lack of awareness of how to obtain information
Gender									
Women	21					✓			Research base in relation to link between gender and use of health services is poor; gender disaggregated data is generally lacking and needs to be collected
Men						✓			
Age									
Older People	1, 3, 9, 13, 24			✓				✓	Feeling of being passed around; fear of repercussions/being struck off;

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									difficult to indentify who to speak to about a concern; inappropriate communication methods; advocacy support is needed - friends and family may be too busy to help; complaints could be avoided by consulting older people earlier about services
Children and Young People	1, 5, 13, 15, 29			✓				✓	Feeling of not being listened to or taken seriously; lectured at; intrusive questioning; reluctance to complain; lack of accessible information; advocacy support is needed; difficulty in accessing advocacy services; lack of understanding of what a complaint is; appropriate and varied information of accessing complaints process is required; need for specialist advocacy

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									provision for particular groups; use of Fraser guidelines for very young children
Religion/Belief/Non-Belief									
People of faith	22, 23						✓		Inclusion of family/relatives is particularly important in some religious communities; involvement of chaplaincy services at times of bereavement
Sexual Orientation									
	6, 8, 27			✓				✓	Lack of understanding of issues relating to sexual orientation; ignorance; demeaning behaviour; making needless assumptions e.g. sexual orientation is responsible for

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									mental health illness; conservative attitudes hinder patient's openness; double stigma; MH problems not felt to be acceptable in the gay community; fears of lack of confidentiality and "being outed"; trying to deal with problems as they arise is the best way – needs more of an effort on the wards and other settings; staff need training in sexual orientation issues; local services to keep lists of support groups, advocates and legal advisers; complaints monitoring information should capture LGB and other equality strands
Transgender									

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
	8, 28		✓				✓		Lack of understanding – many people end up stating they are bisexual as people would not understand the term; “transsexual”; more training for NHS staff needed as many complaints arise from a lack of understanding
Welsh Language									
	7, 30		✓					✓	Lack of engagement/communication in the medium of Welsh; problems of service provision in the Welsh Language; Welsh Language officers/contact points within NHS bodies to assist with investigations and in communications with patients and families; familiarity with advocacy

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									support to assist with Welsh Language complaints; availability of legal support in Welsh; complaint s monitoring information should capture Welsh Language complaints
Other identified groups									
Mental Health Service Users	1, 2, 8, 13			✓				✓	Feelings of being intimidated and unsafe; mistrust of professionals; feelings that professionals close ranks; concerns that future services would be denied; patients want staff to be more proactive in spotting problems; every effort should be made to solve problems as they arise; feeling talked

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
									down to, intimidated; sexual orientation is responsible for mental health illness; double stigma on MH and LGB; MH problems not felt to be acceptable in the gay community advocacy support is needed
Unemployed People	1			✓				✓	Fear of being "looked down on"; treated with less respect
Homeless People	1			✓				✓	Feelings of being judged and labelled as "stupid"; fear of repercussions, being struck off, etc and inability to find alternative services; formality of language; lack of confidentiality; confusion on who to make a complaint to-lack of awareness on how to make a complaint; being fobbed of or blanked

Equality Strand	Evidence Identified (see reference sources set out at Annex A)	Weighting			Relevance				Issues raised by evidence
		Unsatisfactory	Satisfactory	Strong	No apparent relevance	Low	Medium	High	
Carers	1, 6, 9, 13			✓				✓	Fear of repercussions for their loved one; no time to pursue a complaint; concerns not taken seriously; lack of respect; advocacy support is needed
Substance Misusers	1			✓				✓	Feelings that people were judgmental towards them; stigma and lack of respect; lack of privacy; concern about service being withdrawn or struck off; concerns not taken seriously; lack of awareness in how to complain;

Annex A

Reference Sources:

1. Scottish Public Services Ombudsman and Scottish Health Council – Experience and Attitudes in Relation to NHS Complaints since the introduction of the new procedure – December 2006
2. "Putting Things Right Together" – event held in Ferryside, Carmarthenshire with EIRIOL Mental Health Advocacy Service, and service users, professionals and Welsh Assembly Government – July 2008
3. Help the Aged Cymru – engagement meeting with Welsh Assembly Government officials – October 2008
4. Sensory Impairment Group
5. Welsh Assembly Government - A guide to the Model for Delivering advocacy services for children and young people – June 2009
6. Scottish Executive – Making it better: complaints and feedback from patient and carers about NHS services in Scotland – May 2009
7. Welsh Language Board complaint against a Trust in North Wales
8. Stonewall Publications – Double Stigma – 2009 and The Inside-Out Project – March 2007
9. Events held with a variety of patient groups – September 2008
10. HSJ Article 13 April 2009
11. Citizens Advice Bureau comments on reforming the NHS complaints procedure 05 April 2004
12. Gypsies' and Travellers' experience of using urgent care services within Brighton April 2008 - August 2009
13. Wrexham CBC Advocacy works consultation document July 2008
14. East Cambridgeshire and Fenland Health Care Needs Assessment December 2005
15. Red Kite Research & Consultancy - Report of consultations with Children and Young People on New arrangements for handling complaints in health, social care and school and other education settings July 2005
16. WAG - Consultation on Gypsy Traveller Strategy January 2010
17. EQHRC – Making Rights a Reality
18. Welsh Assembly Government – Key messages from focus groups discussing the Single Equality Scheme
19. Welsh Assembly Government – Presentation from Directorate General Equality Lead on the Gypsy Traveller Strategy Consultation

20. Accessible Healthcare for People with Sensory Loss in Wales – final report to the Welsh Assembly Government Health Minister - October 2010 (not yet published)
21. Men's Health Forum for Department of Health - The Gender and Access to Health Services Study –2008
22. Department of Health - Religion or Belief: A practical guide for the NHS – January 2009
23. Welsh Assembly Government – Standards for Spiritual Care in the NHS in Wales – May 2009
24. Age Concern Cymru/Help the Aged Wales – joint response to consultation – April 2010
25. RNIB Cymru – response to consultation – April 2010
26. Children's Commissioner for Wales – response to consultation – March 2010
27. Stonewall Cymru – response to consultation – April 2010
28. Transgender Wales – The Trans Struggle Report – June 2010
29. National Deaf Children's Society – response to consultation – March 2010
30. Welsh Language Board – response to consultation – March 2010

ANNEX 4

The competition filter test	
Question	**Answer yes or no**
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Possibly
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No