

Government Proposed Measure on NHS Redress

Explanatory Memorandum to the Proposed NHS Redress (Wales) Measure 2007

This Explanatory Memorandum has been prepared by the Department for Health and Social Services of the Welsh Assembly Government and is laid before the National Assembly for Wales.

Member's Declaration

In my view the provisions of the NHS Redress (Wales) Measure, introduced by me on the 2nd July 2007 would be within the legislative competence of the National Assembly for Wales.

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Assembly Member in charge of the Proposed Measure

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ANNEX 1 – Explanatory Notes

1. Description

- 1.1 The NHS Redress (Wales) Measure (“the Measure”) is enabling in scope. It will allow Welsh Ministers to create, in subordinate legislation, the detail of the processes to be followed by NHS bodies in Wales when dealing with situations where, following initial investigation, it is determined that there may be negligence but where the resulting compensation is likely to be of relatively low value. This will give patients the ability to secure redress without recourse to legal proceedings in the courts and would form one part of a set of integrated arrangements, which would also include the NHS complaints procedure and the procedures for dealing with incidents. It is envisaged that these would come together to form a holistic package of remedies, including investigation, apologies, remedial action, and in some cases financial compensation for patients who receive treatment or services provided as part of the national health service in Wales.

2. Legislative background

Enabling Power

2.1 The Assembly secured a framework power under section 17 of the NHS Redress Act 2006, setting out regulation-making powers in respect of NHS Redress. Subsequently, and in accordance with powers set out in paragraph 31(2) and (4) of Schedule 11 to the Government of Wales Act 2006, an Order in Council (The National Assembly for Wales (Legislative Competence) (Conversion of Framework Powers) Order 2007) was made. This had the effect of repealing the framework power in section 17 and making provision, by amending Part I of Schedule 5 to the Government of Wales Act 2006, for the new Assembly constituted by that Act to be able to pass an Assembly Measure in relation to NHS Redress. More particularly, the following has been inserted as Matter 9.1 in field 9 of Part I of Schedule 5 to the Government of Wales Act 2006 and forms the basis of the Measure making power:

“Matter 9.1

Provision for and in connection with the provision of redress without recourse to civil proceedings in circumstances in which, under the law of England and Wales, qualifying liability in tort arises in connection with the provision of services (in Wales or elsewhere) as part of the health service in Wales”.

3. Purpose & intended effect of the legislation

Policy background

- 3.1 *Making the Connections*, launched in 2004, set out a vision for public services in Wales and made fair redress one of the key customer service core standards. *Making the Connections* enjoyed general cross-party support and was underpinned by wide degree of consensus across the public sector. Proposals to develop how the health service in Wales responds to things that go wrong therefore sit firmly within that strategic agenda.
- 3.2 The *Healthcare Quality Improvement Plan* (QuIP) published by the Welsh Assembly Government in November 2006 also sets out the development of effective redress as one of the actions required to provide a high quality health service, which continuously learns and improves. In this context, “redress” describes the fair treatment given to an individual, who suffers because of the actions of any body providing health services, whether within the NHS or under NHS commissioning arrangements. The Welsh Assembly Government’s Department for Health and Social Services is taking forward a wider project called *Putting Things Right*, which aims to develop an integrated approach to the handling of and learning from things that go wrong in the NHS in Wales. This Measure forms one part of that wider work.
- 3.3 The Measure is the first to be presented to the third National Assembly for Wales and forms part of a developing “made in Wales” approach to improving the handling of things that go wrong in the health service in Wales. The Assembly took a framework power in the NHS Redress Act 2006 to enable it to decide for itself its own arrangements for the settling of lower value clinical negligence claims. This had been preceded by consultation in 2003 in Wales, which was based on recommendations made by the Chief Medical Officer for England in his report *Making Amends* on reforming the way clinical negligence claims are handled.
- 3.4 The key policy drivers for the proposed reforms are:
- the current system is perceived to be complex and inconsistent – apparently similar cases may have different outcomes and often are slow to resolve;
 - the current system is costly both in terms of legal fees and diversion of staff from patient care. It also has an adverse effect upon NHS staff morale and upon public confidence;
 - patients are often dissatisfied with the lack of explanations and apologies they receive following an incident. they often do not feel reassured that action has been taken to prevent the same incident happening again; and

- the system encourages defensiveness and secrecy amongst NHS bodies which stands in the way of learning and improvement in the health service.

Objective of the legislation

- 3.5 The Measure will give powers to Welsh Ministers to enable them to require providers or commissioners of services as part of the national health service in Wales to consider settling lower value clinical negligence claims without recourse to legal proceedings, as part of a package of remedies available in handling things that go wrong. Its objective is to ensure a fairer and more transparent and accessible choice for patients.
- 3.6 The intention is to create a framework and culture in which, when mistakes arise during the provision of NHS services, NHS bodies in Wales are better able to learn from those mistakes and take action both to put things right and to avoid repetition of such mistakes in the future. Presently, the existing, somewhat fragmented, arrangements do not present the best option for achieving these aims.
- 3.7 Alternative options need to be available to patients who have suffered as a result of clinical negligence. The existing, and by far most common option of resorting to litigation, is one that may discourage some patients accessing justice for a number of reasons. Patients may, due to the financial eligibility criteria, be unable to obtain public funding through legal aid, and may have no other means of funding a potential claim. Some patients also find the prospect of seeking redress through the legal system intimidating or daunting in terms of the time scales involved and the personal stress that the process inevitably entails.
- 3.8 Current arrangements do not fully encourage a culture of putting things right and of learning from mistakes. The legal system is adversarial. It has the potential to encourage those who are at the receiving end of it to act defensively and thus reduce the opportunity to learn lessons from mistakes that have been made. Instead, we would like to develop an approach that encourages learning and more fully meet the needs of the patients and staff involved, encompasses early and thorough investigation, full and suitable explanations and apologies and the appropriate awarding of financial compensation at a local level.
- 3.9 This Measure and the sub-ordinate legislation made under it will provide for a particular emphasis on settling lower value clinical negligence claims without the need for formal legal proceedings. This will mean that for the first time, a legislative framework will be in place which will require Welsh NHS bodies to consider this redress option in appropriate cases. The aim is to give NHS bodies the tools to remedy their own mistakes and to learn from them.

Territorial application

3.10 The Measure will apply in relation to Wales. It will include the ability to make regulations, which will have effect where health care has been commissioned in relation to Welsh patient from providers situated outside Wales.

Summary and explanation of each provision in the Measure

3.11 A full Explanatory Note is provided at Annex 1, describing the effect of each section of the draft Measure.

4. Consultation

- 4.1 There has been no formal consultation on the policy objectives of the Measure or on the detail contained in it. Formal consultation will take place in 2008, subject to the Measure being passed, when the detail of the new arrangements, to be set out in regulations, will be presented in full.
- 4.2 There was however a consultation on the recommendations of the *Making Amends* report in 2003 which revealed support for reforming the way in which clinical negligence claims are dealt with. There has been subsequent engagement with NHS and other partners, including Community Health Council complaints advocates during the passage of the NHS Redress Bill and as part of the *Putting Things Right* project. The message has been that there is considerable support for looking at this area and for becoming involved in the development of the detail.

5. Power to make subordinate legislation

- 5.1 The draft Measure contains wide enabling powers for Welsh Ministers to implement and set out the detail of the redress arrangements in regulations. It is therefore acknowledged that there will be considerable interest in relation to Welsh Ministers' intentions for redress as contained in those regulations.
- 5.2 The detail of the policy in relation to NHS Redress is currently under development and NHS bodies and other interested parties are playing an active role in identifying what needs to change in the current processes and what arrangements need to be put in place for the future. A steering group, chaired by a Trust Chief Executive, has been established to oversee this work which will continue for some time before, during and after the introduction of the Measure. It is felt that such a process will be key to the future success of any arrangements. For this reason, the regulation making powers set out in the Measure are widely drawn to enable the results of this work to be taken into account in the drafting of the regulations. Because of the timescales involved in this work, the draft regulations will not be considered alongside the draft Measure.
- 5.3 However, it is likely that future regulations will make specific provision about:
- the organisations which will have to operate the arrangements;
 - who will be able to access the arrangements;
 - the form of any compensation and circumstances when different forms of compensation may be offered;
 - financial limits;
 - who will support patients both in the provision of legal advice at various points along the way and in terms of general assistance, by way of representation (known as advocacy).
- 5.4 The draft Measure also contains provisions that would confer power on Welsh Ministers to make amendments to various Acts of Parliament and statutory instruments consequential on changes required as a result of the regulations. The scope of these powers is limited by the extent of the Measure making power to amendments which will be consequential on the introduction of NHS Redress.
- 5.5 It is appreciated that such powers to make consequential amendments are not granted lightly, however it is felt that having such powers will preserve flexibility and will allow Welsh Ministers to make appropriate changes to primary legislation when the policy to be set out in the regulations, is fully developed and consulted upon.
- 5.6 By way of example, Welsh Ministers might make use of these amending powers to make changes to the Public Service Ombudsman Wales Act

2005 to give the Ombudsman jurisdiction to investigate complaints about maladministration arising out of the operation of the NHS Redress arrangements. Welsh Ministers may also need to exercise the power to make appropriate amendments to section 182 of the National Health Service (Wales) Act 2006 which deals with the provision of independent advocacy services, in order to ensure that advocacy is made available to persons seeking redress.

5.7 In recognition of the wide scope of the powers contained in the draft Measure, and in order to provide opportunity for further scrutiny by the National Assembly, the affirmative procedure will be used on each occasion that regulations are made under section 12 that modify an Act of Parliament or an Assembly Measure and on each occasion that regulations make provision under sections 1(4)(b); 1(5); 3 and 5. In addition, the affirmative procedure will be used for the first set of regulations to make provision under sections 2, 4, 6, 7 and 9. In any case, the first set of regulations made under the Measure, irrespective of which sections are covered, will be made under the affirmative procedure. Prior to regulations being put before the Assembly, there would be a formal consultation on the detail of the new arrangements and how the regulations would underpin them.

5.8 The regulation making powers that are being sought in the Measure are wide enough to apply the NHS Redress arrangement to primary care. However, because the indemnity arrangements for GPs, dentists, opticians and pharmacists are different from those for hospital clinicians, there is the option to make regulations covering primary care separately from the main arrangements applying to hospital and specialised commissioned care. This would give more time to work out the practical details and conduct the necessary negotiations with the contractor professions and their medical defence unions.

6. Regulatory Impact Assessment (RIA)

6.1 A Regulatory Impact Assessment has been completed for this Measure and follows at Part 2.

PART 2 – REGULATORY IMPACT ASSESSMENT

7. Options

7.1 The following options are available:

Option 1: Do nothing

Option 2: Introduce alternative arrangements through guidance with no further legislation

Option 3: Introduce an Assembly Measure

Option 1 – Do nothing

7.2 The current legal system for handling financial redress for clinical negligence claims is well established and understood. However, doing nothing would produce no additional benefits. Maintaining the current system would not:

- provide a real alternative to litigation for the cases that would qualify to be heard under the redress arrangements;
- address the delays experienced in, or legal costs incurred under, the current system;
- lead to a more consistent response to patients when things go wrong;
- place the emphasis on putting things right for patients as a matter of course and provide the explanation, apologies and reassurance that patients say they want; or
- contribute to a culture of learning in the NHS, providing impetus for wider service improvement.

7.3 Doing nothing maintains a situation in which a number of people are deterred from obtaining an outcome they deserve. Whilst longer-term cultural change might deliver an improved patient experience, the system would remain skewed in favour of the articulate, the more motivated and those with sufficient resources, time and energy to follow through their complaints. In practice, the proposed arrangements will be about putting things right for complainants as a matter of routine. Providing a real alternative to litigation for the cases that qualify for redress under the arrangements will address the delays and costs that are part and parcel of the current system and, over time, reduce legal costs occasioned both in bringing and defending claims.

Option 2 – Introduce alternative arrangements without recourse to legislation

7.4 It would be possible to continue to make improvements to the way in which complaints, claims and incidents are handled without recourse to

primary legislation. These improvements would be largely confined to building on work already underway in Wales on clinical negligence and claims handling, and on improvements to the complaints procedure. Some of this is described below.

Work already underway in the better handling of clinical negligence claims:

Speedy Resolution Scheme Pilot Project for Clinical Negligence Claims

7.5 The Scheme was devised by a working party constituted by the Welsh Assembly Government. It is a joint expert, fixed timetable, fixed fee scheme that is open to claims against Welsh NHS Trusts that are worth between £5,000 and £15,000. The scheme was launched on 1 February 2005.

7.6 The Welsh Assembly Government hopes that the scheme will achieve four basic policy objectives:

- A reduction in the length of time taken to resolve clinical negligence claims that qualify for entry to the scheme;
- A reduction in the costs of settling such claims;
- An improvement in lessons learned from individual cases and
- Increased provision of explanation of treatment

7.7 The scheme will be evaluated, by the autumn of 2007, as part of the *Putting Things Right* project and a decision on whether or not to continue the scheme and possibly extend it will be made. Whilst the aims of the Speedy Resolution Scheme do mirror many of the aims of the proposed redress arrangements, it is still a form of litigation, albeit shortened. As such, for some patients, it will carry many of the deterrents outlined above, which potentially prevent people from taking legal action. It is also limited in its scope to provide alternative means of settlement. Subject to its evaluation, the Speedy Resolution Scheme may have a useful continuing role as an alternative for those people who do want to pursue the litigation route instead of any NHS-led redress arrangements.

Alternative Dispute Resolution (ADR) Schemes

7.8 Alternative Dispute Resolution (ADR) uses conciliation and mediation techniques to resolve problems, rather than resorting to confrontational litigation. Round table meetings are arranged either with the solicitor and the claimant or with barristers for both parties accompanied by the claimant and NHS Trust representative.

7.9 The benefits of ADR are that it is likely to involve less cost, be quicker and is confidential. It also aims to ensure that the doctor-patient relationship is preserved.

7.10 The disadvantage of ADR is that the claim has to be one that is capable of resolution, for example, where liability and causation is agreed

by both sides. Where mediation through ADR is used, this has mixed success because complainants tend to assume the offer of mediation means that the Trust has only a weak case. Where it is explained that mediation is being offered as an opportunity to understand what has happened, it is sometimes rejected. Mediation can be costly particularly if it is unsuccessful and the Trust then has to pay to defend a claim either brought or continued by the claimant.

Further work to embed the Being Open policy across the NHS in Wales

- 7.11 The National Patient Safety Agency (NPSA) has developed a policy on openness and honesty following patient safety incidents. This policy is entitled *Being Open* and involves apologising and explaining to patients who have been involved in a patient safety incident (and/or their carers). It ensures communication is open, honest and occurs as soon as possible following an incident and encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers.
- 7.12 The recommendations for the introduction and integration of the *Being Open* policy are that NHS Trusts should, by June 2006, have developed a local policy which is adapted to suit local requirements. These policies should be integrated with existing risk management and clinical governance structures. Awareness of the policy should be raised among healthcare staff through the provision of the appropriate information and support. NHS organisations are at various stages of development with this work and more information is being sought as part of the *Putting Things Right* project.
- 7.13 All of these developments are positive and moving in the right direction, however, in and of themselves, they fall short of the higher aims of the proposed arrangements in providing a real alternative to litigation and access to appropriate redress.

Option 3 – Introduce an Assembly Measure

- 7.14 This option best meets the policy intentions of creating a culture in which NHS bodies deal routinely and consistently with patients who have suffered harm and are more able to learn from their mistakes. There is enthusiasm from those involved with the existing systems and procedures for complaints, clinical negligence and incident handling to look for better ways of working. This, coupled with the new powers available to the Assembly, means that now appears to be a very good time to act to make real improvements and build new arrangements that will deliver better responses for patients. The specific benefits of the proposals contained in the draft Measure include:

- improved learning from mistakes at a local level, better and more effective investigations, increased focus on explanations and apologies;
- a proactive approach to redress, where local organisations must actively consider this option in appropriate cases;
- the binding nature of the offer and acceptance of redress remedies through a legal contract, thus avoiding recourse to the courts and the attendant costs;
- provision of legal advice and advocacy support without charge to the individual seeking redress.

7.15 Things that go wrong can range from a fairly minor incident that could potentially be dealt with quickly to clinical errors or systems failures resulting in serious harm or even death. In recent years more work has focussed on the need to improve safety, learn from mistakes and to be open with people in such situations. The serious incident reporting system is building up confidence in NHS organisations to report issues and slowly the culture is changing. Nevertheless, the fact remains that people who complain or who believe they have been harmed often feel that they have been dealt with poorly and often made to fight for a fair outcome, whether it be an explanation, apology, remedial treatment, an assurance that action will be taken to prevent the same thing from happening to someone else, or, where appropriate, financial compensation.

7.16 Whether an issue should be handled as a complaint, a claim or an incident under the reporting arrangements is sometimes unclear. Cases where there may have been clinical negligence and where financial compensation may be appropriate are often not recognised or acted upon, unless and until solicitors are instructed to commence investigations with a view to initiating legal proceedings. There has been a general reluctance to tackle such issues at an early stage to bring about resolution that is positive and from which lasting lessons can be learned. This is not altogether surprising given that such situations can cause considerable anxiety for staff and poor publicity for the organisation involved. As a result, there has been a tendency to respond defensively rather than openly. This situation is changing through the implementation of policies such as *Being Open*, as indicated above, but with further impetus, provided for in legislation, NHS bodies in Wales will be empowered to take a more proactive stance.

7.17 The arrangement which is envisaged has a common point of entry for dealing with matters that go wrong which crosses complaints, clinical negligence and incidents. Common access would enable NHS managers to decide at an early stage, in conjunction with complainants, the most effective way of handling a matter, and the level of investigation required.

7.18 Developing the skills of staff to be able to undertake appropriate investigations will be of great importance, both in terms of building on existing skills and experience, and the acquisition of new areas of

expertise. This may be achieved through the training and development of existing staff and/or the recruitment of further staff.

7.19 The Measure will form one aspect of the legislation that will underpin these arrangements. The Assembly has already secured regulation-making powers (now exercisable by Welsh Ministers) in respect of complaints in the Health and Social Care (Community Health and Standards) Act 2003. The Measure will confer powers on Welsh Ministers, to enable them to set out in regulations requirements for the implementation arrangements covering lower value cases of clinical negligence. In exercising these regulation-making powers alongside each other, Welsh Ministers will be able to ensure that they knit together to underpin the integrated arrangements envisaged.

8. Costs & benefits

Option 1: Doing Nothing

Benefits:

8.1 There is little benefit in doing nothing. The system will continue largely as present, with the general trend favouring more openness and proactive approaches, but there will be little impetus to develop further and less consistency in leaving things to develop in an ad hoc way.

Costs:

8.2 There is often the view expressed anecdotally that litigation numbers and costs are high and rising and that people are only too willing to pursue claims against the NHS. However, the number of current claims recorded in Wales does not support the “litigation culture” view. In fact the actual numbers of claims in Wales shows little variation over an 18-month period.

8.3 There is, however, an acceptance that low value claims often cost the NHS more than they might, both financially and in terms of time out of the service for health service personnel. The legal costs can, and sometimes do exceed the value of the settlement made to the patient. This is often due to the lengthy, and sometimes cumbersome, legal process that is to be followed.

8.4 The concern over the cost issue and the often lengthy legal process were two of the reasons cited for the development of the Speedy Resolution Scheme (SRS) currently being piloted, as discussed earlier, but there is not the scope within this for exploring alternative remedies for patients. The SRS also requires the intervention of solicitors on both the NHS and patient side and therefore removes the potential for early settlement through negotiation between the patient and the NHS organisation.

8.5 Clinical negligence settlements within the NHS in Wales cost over £27m (excluding legal costs) in 2005/2006 which is indeed considerable, but of equal importance is the cost to both patient and staff of the often protracted and stressful process. To accept the status quo would be to accept the probability of a continuation of the pattern of current claims, to ignore both the potential for cost saving, and also the possibility that patients’ needs in some cases could be better met by alternative arrangements.

Option 2: Issue guidance/build on what is already happening

Benefits:

8.6 This would be of some value but would not provide the focus the Assembly Government is looking for in terms of making improvements in this whole area.

Costs:

8.7 Many of the comments made in relation to the costs of doing nothing apply equally well here in terms of not realising the potential benefits. This option may or may not be influential on costs, depending on how vigorously any revised guidance were adhered to. It may not provide the impetus for trusts to develop their approach to the management of small claims and empower them sufficiently to attempt settlement without the need for resorting to legal remedies.

Option 3: Introduce a Measure.

Benefits:

8.8 The Measure will provide the Welsh Ministers with the power to introduce arrangements, which will lead to a more consistent response to patients when things go wrong. The emphasis will be placed on putting things right for patients as a matter of course, providing the explanations, apologies and reassurances that patients say they want¹, and providing financial compensation where appropriate. The Measure will give the Welsh Ministers regulation making powers to introduce a less adversarial approach to putting things right and create a culture in which NHS bodies are more readily able to learn from its mistakes.

8.9 Initial work suggests that there is also the potential for savings of £750,000 per annum (see below). However, this figure must be treated with caution, as it is a very early assessment.

Costs:

8.10 The financial costs are currently uncertain and they form part of the detail to be identified by the formal project established to develop these arrangements in Wales.

8.11 However, financial modelling work done in England, expects that the NHS Redress Scheme (which is likely to have similar financial limits to any Welsh arrangements) there will initially increase spending, for the reason that improving access to remedies when things go wrong is likely

¹ Patients want: An apology (34%); Explanations (23%); Support with the consequences (17%); Financial compensation (11%); Disciplinary action (6%) **Source: MORI/DH**

to bring claims into the system which otherwise may not have been pursued. However, in the longer term, savings are expected from a reduction in legal costs and improved learning from mistakes, resulting in fewer negligence claims. Much depends on how many new claims are received, and the English figures predict a huge variation, from a potential saving of £7 million where only small increases in redress claims were seen, to additional costs of £48 million where large increases in claims were seen.

- 8.12 Similar effects are expected in Wales through the change of emphasis to earlier and better investigation. Some initial work done by a firm of cost actuaries for the Welsh Risk Pool in assessing the potential costs of increased claims under new arrangements, puts the financial impact at between a potential saving of £750,000 per annum to additional costs of £3 million. These figures must be treated with caution, as they are very early assessments.
- 8.13 There will be significant costs associated with the training and development of staff across organisations to undertake proper investigations and to deal with issues appropriately. These costs have not yet been quantified. There might also be small costs arising from initial investigations initiated into potential claims which do not then proceed under the arrangements for various reasons, however it would be difficult to predict at this stage the magnitude of such costs.
- 8.14 It is the intention that legal advice and advocacy support for people who have their case considered under the redress arrangements will be provided free of charge. Again, it will be for the project to identify the mechanisms by which these services might be provided and the likely costs of doing so.
- 8.15 Any additional costs under these new arrangements must be met from within future budget settlements for the Health and Social Services portfolio.
- 8.16 In terms of the impact on legal firms involved in medical negligence work, this legislation is unlikely to impose any additional costs. However, as lower value claims make up a significant part of the clinical negligence solicitors' workload, there is the potential that at least some of these claims would be dealt with under new arrangements and thus be diverted away from legal firms. We can therefore conclude that there could be some loss of income to legal 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.
- 8.17 It is worth noting that during consultation carried out in England for the NHS Redress Scheme there, it became clear that the proposals had general support from both the Law Society and the Law Reform

Committee of the Bar Council – no concerns over impacts on legal businesses were raised.

8.18 It is not anticipated that arrangements to be introduced under powers contained in the Measure would impact on local government.

8.19 It is not anticipated that arrangements would impact on the voluntary sector in Wales.

8.20 It should be noted that a further, more detailed Financial Impact Assessment was put before the Assembly in February 2008.

9. Competition Assessment

- 9.1 The impact of any new arrangements on small businesses will be insignificant and there will be no impact on local government or the voluntary sector.

10. Post implementation review

10.1 Monitoring and review details will be set out in regulations to be made as a result of the Measure.

Annex 1

Explanatory Notes

Introduction

1. These explanatory notes relate to the draft NHS Redress (Wales) Measure as introduced in the National Assembly for Wales on 2nd July 2007. The Welsh Assembly Government's Department for Health and Social Services has prepared them in order to assist the reader of the draft Measure and to help inform debate on it. They do not form part of the draft Measure and have not been endorsed by the National Assembly for Wales.
2. The notes need to be read in conjunction with the draft Measure. They are not, and are not meant to be, a comprehensive description of the Measure. So where a section or part of a section does not seem to require any explanation or comment, none is given.

Summary and background

3. *Making the Connections*, launched in 2004, set out a vision for public services in Wales and made fair redress one of the key customer service core standards. *Making the Connections* enjoyed general cross-party support and was underpinned by wide degree of consensus across the public sector. Proposals to develop how the health service in Wales responds to things that go wrong therefore sit firmly within that strategic agenda.
4. The *Healthcare Quality Improvement Plan* (QuIP) published by the Assembly Government in November 2006 also sets out the development of effective redress as one of the actions required to provide a high quality health service, which continuously learns and improves. In this context, "redress" describes the fair treatment given to an individual who suffers because of the actions of any body providing health services, whether within the NHS or under NHS commissioning arrangements. The Welsh Assembly Government's Department for Health and Social Services is taking forward a wider project called *Putting Things Right*, which aims to develop an integrated approach to the handling of and learning from things that go wrong in the NHS in Wales. This Measure forms one part of that wider work.
5. The Measure sets out regulation-making powers for Welsh Ministers to establish arrangements to enable the NHS in Wales to settle, without the need to commence court proceedings, certain claims which arise in connection with services provided to patients as part of the health service in Wales, wherever those services are provided. It sets out which organisations would have to implement these arrangements.

Territorial Application

6. The Measure applies in relation to Wales. It will include the ability to make regulations, which will have effect where health care has been commissioned in relation to Welsh patients from providers situated outside Wales.

Commentary on Sections

Section 1: Power of Welsh Ministers to make regulations in respect of NHS Redress

7. *Subsection (1)* sets out the general principle that Welsh Ministers may make regulations to provide for NHS Redress arrangements which will enable matters to be settled without having to go to court where a qualifying liability in tort arises. *Subsection (2)* provides that the arrangements will apply to cases where there is liability in tort arising out of health services provided as part of the National Health Service in Wales, or elsewhere provided that it is commissioned as part of the health service for a person resident in Wales. As set out in *subsection (3)*, the arrangements will apply to liability in tort arising on the part of:
 - NHS Trusts in Wales;
 - Local Health Boards;
 - Special Health Authorities;
 - Welsh Ministers;
 - Any body or person providing or arranging for the provision of services in Wales as a result of an arrangement with any of the above bodies. This means that general practitioners; dentists, pharmacists and ophthalmologists providing NHS care or independent hospitals commissioned to provide care as part of the NHS may incur liability.
8. *Subsection (4)* provides that liabilities in tort must be in respect of personal injury or loss arising out of a breach of duty of care, in connection with the diagnosis of illness or of care and treatment provided. Therefore redress will normally apply in relation to patients receiving NHS care. *Subsection (4)* specifically provides that this liability will be owed as a result of an act or omission by a healthcare professional, but the Welsh Ministers have the power to specify any other body or person who might also incur liability.
9. Arrangements would not be restricted to claims by patients. So long as claims otherwise fall within the definition in *subsection (4)*, it may cover claims that could be brought following the death of a patient by virtue of the Law Reform (Miscellaneous Provisions) Act 1934 (which provides that where a person has a cause of action and that person dies, the action may be pursued for the benefit of his estate). It may also cover claims brought by the dependents of a deceased patient under the Fatal Accidents Act 1976. This provides that where a person's death is caused by any wrongful act, neglect or default which is such that, had

death not occurred, it would have entitled the person injured to maintain an action and recover damages in respect of the injury, liability to an action for damages continues for the benefit of dependents of the person who died, such as a wife, child or civil partner.

10. *Subsection (6)* provides that people working under a contract of employment will not be personally held liable for negligence, rather it would be their employer who would be liable for their actions.

Section 2: Redress under the regulations

11. This section sets out in more detail the type of provision that Welsh Ministers may make in respect of redress arrangements. *Subsection (1)* provides that Welsh Ministers may make whatever arrangements in regulations they think appropriate about redress, subject to the provisions of *subsections (2), (3) and (6)(b)*. Those subsections state that the regulations must provide:

- For redress to comprise of the making of an offer of financial compensation; giving explanations, written apologies and a report on action and learning and that these can be provided in any combination (*subsection (2)*);
- That the arrangements must not apply to a case which is already or which has been the subject of legal proceedings (*subsection (3)*) and
- That any regulations which provide for financial compensation must specify an upper limit on the amount to be offered in respect of pain and suffering (general damages), if no overall upper limit is set (*subsection (6)(b)*). It is currently envisaged that any arrangements would seek to set an overall limit encompassing general and special damages to ensure that more complex and high value claims are dealt with by claims specialists and not through the local arrangements.

12. *Subsection (4)* provides that the regulations may allow for compensation to be offered in the form of remedial treatment and/or financial compensation, set out in a contract with the patient. This would provide real guarantees to the patient that they will receive the remedial care they need, within a specified time. If financial compensation is to be offered, then *subsection (5)* provides that the regulations may specify the matters in respect of which financial compensation may be offered and how the assessment of compensation is to be carried out. *Subsection (6)(a)* provides that an upper limit may be placed on the amount of financial compensation.

Section 3: Accessing redress

13. This section makes provision for Welsh Ministers to make whatever arrangements they see as appropriate about accessing the redress arrangements. *Subsection (2)* provides that the regulations may specify who may access the arrangements. This might be the patient

or someone on their behalf, or the organisation concerned might initiate the arrangements on the patient's behalf and with their consent. The regulations may also make provision for time limits in relation to accessing redress.

Section 4: Duty to consider potential access to redress arrangements

14. This section provides that Welsh Ministers may specify in regulations that any body or person who is reviewing a specific case relating to a patient should actively consider whether redress may be available in relation to that case.

Section 5: Method of delivering redress

15. This section sets out in more detail the type of provision Welsh Ministers may make in regulations for how the arrangements will operate. *Subsection (1)* provides that Welsh Ministers may make whatever arrangements in regulations they think fit about how redress is to be delivered, subject to the provisions of *subsections (3), (5) and (6)*. Those subsections state that the regulations must provide:

- For time limits in respect of the investigation and conclusion of cases being dealt with under the NHS Redress arrangements; for the findings of any investigation to be recorded in a report and for a copy of that report to be available to the person seeking redress (*subsection (3)*);
- For any settlement under the arrangements to include a waiver of the right to bring civil proceedings in respect of the same issues (*subsection (5)*); and
- That if legal proceedings are started in respect of the same issues, then the redress arrangements can no longer apply. In such cases, any investigation already started would have to be discontinued (*subsection (6)*).

16. *Subsection (2)* states that the regulations may provide for details around investigations and settlements. *Subsection (4)* provides that the regulations may specify that a copy of an investigation report need not be provided in certain circumstances.

Section 6: Suspension of limitation period

17. The Limitation Act 1980 provides that a person cannot normally bring court proceedings for personal injury more than three years from the date on which the harm arose or the patient had knowledge of that harm. This section ensures that the regulations must provide for the suspension of any limitation period applying to cases that are being considered under the arrangements. In doing so, it means that patients will not be prejudiced or prevented from taking matters to court (if they choose not to accept any offer) by having to wait for the outcome of an investigation under the redress arrangements.

Section 7: Legal advice, etc.

18. This section sets out that Welsh Ministers may make any provisions they think fit in regulations for the provision of legal advice or other services, including expert medical opinion, to people using the redress arrangements (*subsection 1*). The regulations must at the very least ensure that people have access to legal advice about any offer, refusal to make an offer or any settlement agreement (*subsection 2*). *Subsection (3)* sets out that the regulations may specify that whoever provides legal advice should be included in a list. *Subsection (4)* provides that if the advice of a medical expert is to be commissioned, then effectively this would be done jointly by the NHS body and the individual seeking redress.

Section 8: Assistance for individuals seeking redress

19. This section places a duty on Welsh Ministers to arrange reasonable assistance for people seeking or intending to seek redress under the arrangements. *Subsection (4)* provides that the assistance should be independent of the person or body who is the subject of the complaint. This assistance is different from the legal advice which is provided for under Section 7 and is more akin to general assistance or advice for people who feel they may want to talk through their situation before taking further action or advocacy and representation at meetings, etc.

Section 9: Functions with regard to redress arrangements

20. This section allows Welsh Ministers to set out in regulations the functions that any person or body in the health service in Wales shall have regarding the operation of the redress arrangements. In particular, *subsection (2)* sets out that these may include functions around accessing redress, making payments, monitoring and collection of data, etc.

21. *Subsection (3)* makes provision for the keeping of records and for the conferring on any body or person responsibility for overseeing that the arrangements are being carried out properly and ensuring that lessons are learnt. This section also requires the regulations to make provision requiring such body or person as is specified to publish an annual report about the cases it deals with and the lessons learnt (*subsection (4)*) and to have regard to advice and guidance issued by Welsh Ministers (*subsection (6)*). The section also allows for regulations to provide for functions to be exercised jointly (*subsection (5)*).

Section 10: Complaints

22. This section amends section 113(2) of the Health and Social Care (Community Health and Standards) Act 2003 to include complaints about the provision of redress arrangements. This means that people will have the right to complain about the administration of the redress

arrangement (i.e. whether a decision was properly taken). This is not the same as disagreeing with a decision that has been properly made and there is no right of appeal in such situations. If the claimant disagrees with a decision that has been properly made, then they retain the right to take legal action.

Section 11: Orders and regulations

23. This section makes provision about Welsh Ministers' regulation making powers under the Measure. In particular, *subsection (6)* provides that the affirmative procedure will be used on each occasion that regulations are made under section 12 that modify an Act of Parliament or an Assembly Measure and on each occasion that regulations make provision under sections 1(4)(b); 1(5); 3 and 5. In addition, the affirmative procedure will be used for the first set of regulations to make provision under sections 2, 4, 6, 7 and 9. In any case, the first set of regulations made under the Measure, irrespective of which sections are covered, will be made under the affirmative procedure.

Section 12: Power to make further supplementary and consequential provision, etc.

24. This section allows Welsh Ministers to make any other related provisions to give effect to the Measure. In particular, *subsection (2)* allows Welsh Ministers to amend or repeal any Act of Parliament and statutory instruments consequential on changes required as a result of the regulations. The scope of these powers is limited by the extent of the Measure making power to amendments which are related to NHS Redress.

Section 13: Interpretation

25. Section 13 provides definitions for certain expressions used in the Measure.

Section 14: Short title and commencement

26. This states the name by which the Measure will be known. It also makes provision for Ministers to commence sections at different times from each other.