



National Assembly for Wales  
Cynulliad Cenedlaethol Cymru

## Proposed NHS Redress (Wales) Measure 2007

### **Abstract**

This paper provides briefing for the Stage 3 plenary consideration of Members' amendments to the first Measure to be brought before the National Assembly since the enactment of the *Government of Wales Act 2006*.

The paper includes information on the Stage 2 amendments and the recommendations from the Stage 1 report. It also includes a chronology of the process with links to key documents and background information on the *Proposed Measure*.

April 2008





# Proposed NHS Redress (Wales) Measure 2007

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April 2008

Paper number: 08/033

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## Summary

The National Assembly's first piece of legislation under the new powers, the *Proposed NHS Redress (Wales) Measure 2007 (The Proposed Measure)*,<sup>1</sup> was introduced on 3 July 2007 by the Minister for Health and Social Services who gave a plenary statement about the Government's intentions for redress powers.<sup>2</sup>

I am seeking regulation-making powers in this Measure, so that we can develop better arrangements for settling low-value clinical negligence claims without the need for legal action.

The National Assembly previously secured a broad framework power under section 17 of the *NHS Redress Act 2006* enabling it, by regulations, to make any provision that could be made by an Act of Parliament (subject to certain limitations) to provide a mechanism for the out-of-court settlement of claims in tort arising out of NHS services in Wales.

Enactment of the *Government of Wales Act 2006* (GOWA 2006) on 6 June 2007 gave new legislative powers to the National Assembly, and the *National Assembly for Wales (Legislative Competence) (Conversion of Framework Powers) Order 2007* transferred powers in relation to NHS redress to the Assembly. The *Order* added Matter 9.1 to Field 9 to Schedule 5 of the *GOWA 2006* and gave the Assembly the necessary power to make the Measure.<sup>3</sup>

The *Proposed Measure* has completed Stages 1 and 2 and progressed to Stage 3.

This paper has been produced to assist Members with tabling amendments to the *Proposed NHS Redress (Wales) Measure 2007* at Stage 3. The paper includes information on the Stage 2 amendments and the recommendations from the Stage 1 report together with a chronology of the process with links to key documents and background information on the *Proposed Measure*.

The *Proposed NHS Redress (Wales) Measure 2007 (Proposed Measure)*, which the Minister initially intended to apply only to hospital and specialised commissioned care (but with provision for application to be made to primary care, i.e. primary dental, primary

<sup>1</sup>Welsh Assembly Government, Proposed NHS Redress (Wales) Measure 2007, <http://www.assemblywales.org/ms-ld6697-e.pdf?langoption=3&ttl=MS-LD6697%20%20Proposed%20NHS%20Redress%20%28Wales%29%20Measure%202007>

<sup>2</sup>RoP, p37-61, 3 July 2007 <http://www.assemblywales.org/bus-home/bus-chamber/bus-chamber-third-assembly-rop/rop070703qv.pdf?langoption=3&ttl=The%20Record%20%28PDF%20402kb%29>

<sup>3</sup>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.

medical, general ophthalmic, and local pharmaceutical services, by future regulations) was introduced to the Assembly on 3 July 2007.

During Committee Stage 1, two overarching issues were the lack of detail in the Measure about the redress scheme and how it would be structured and implemented, and the Financial Impact Assessment and costs.

Publication of the Committee Stage 1 Report was delayed until the Minister for Health and Social Services produced a report from the Working Parties set up to consider the various aspects of the Redress Scheme towards the end of January 2008.

Committee Stage 2 was completed on 11 March 2008, and Stage 3 commenced thereafter. Forthcoming key dates for Stage 3 are:

<b>29 Apr 2008</b>	<b>Last day for tabling Stage 3 amendments to the <i>Proposed Measure</i></b>
<b>06 May 2008</b>	<b>Stage 3 Plenary – consideration of amendments</b>

Below are other key dates in the process together with links to relevant documents:

17 Apr 2008	<a href="#">Revised Explanatory Memorandum</a> (with Stage 2 Amendments) laid
16 Apr 2008	Finance Committee <a href="#">Supplementary Report</a>
12 Mar 2008	<a href="#">Proposed NHS Redress (Wales) Measure 2007</a> (as amended at Stage 2)
11 Mar 2008	Stage 2 Committee: Session 2, <a href="#">proceedings</a>
04 Mar 2008	Stage 2 Committee: Session 1, <a href="#">proceedings</a>
22/26 Feb 2008	<a href="#">Amendments</a> to the Stage 1 report tabled

- 21 Feb 2008 [Final Assessment](#) of the Financial Impact Assessment
- 30 Jan 2008 Commencement of Committee Stage 2
- 29 Jan 2008 [Plenary debate](#) on Committee Stage 1
- 24 Jan 2008 [Committee Stage 1](#) report was laid
- 15 Nov 2007 Proposed Measure Committee agreed to seek a postponement (granted) of Committee Stage 2 until a report of progress from the Working Parties considering the Redress Scheme was received.
- 13 Nov 2007 Subordinate Legislation [Final Report](#) considered
- 12 Jul 2007 The Proposed NHS Redress (Wales) Measure Committee agreed consultation process – [consultation letter](#)
- 03 Jul 2007 [Proposed NHS Redress \(Wales\) Measure](#) introduced in [Plenary](#) by the Minister for Health and Social Services  
[Explanatory Memorandum](#) also produced

Web pages:

Proposed Measure [Committee](#)

[Proposed Measure](#)

Stage 2 [amendments](#)





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## Proposed NHS Redress (Wales) Measure 2007

### 1 STAGE 3 AMENDMENTS

Stage 3 of the process commenced on 12 March 2008<sup>4</sup> allowing a period for Assembly Members to table amendments to the *Proposed Measure* with Stage 2 amendments (Sections 1-14) (*Proposed Amended Measure*)<sup>5</sup>. The closing date for Stage 3 amendments is 29 April 2008.

A copy of the *Proposed Measure* (as amended) was published on 12 March, 2008, and the Finance Committee provided a Supplementary Report<sup>6</sup> dated 16 April 2008. A revised Explanatory Memorandum taking account of Stage 2 amendments<sup>7</sup> was laid on Thursday, 17 April 2008.

Stage 3 amendments will be considered in Plenary on Tuesday 6 May 2008.

### 2 COMMITTEE STAGE 2 – AMENDMENTS

Committee Stage 2 commenced on 30 January 2008. Eighteen amendments were tabled by Committee Members on 22 and 26 February 2008<sup>8</sup> and considered at two meetings held on 4<sup>9</sup> and 11 March 2008<sup>10</sup>. Twelve amendments were agreed by the Committee (*see below*). Many of the amendments passed at Stage 2 were technical in nature, however the amendments in relation to Section 5: Method of delivering redress and Section 11: Orders and regulations, were substantive government amendments which gave effect to recommendations made in the Stage 1 Committee's report.

The *Proposed Measure* (as amended) contains these changes which are marked in the document by vertical lines in the right-hand column.

<sup>4</sup>Stage 3 Amendments <http://www.assemblywales.org/bus-home/bus-legislation/bus-leg-measures/bus-legislative-meas-nhsrrev/bus-legislation-meas-nhsr-stage3.htm>

<sup>5</sup>Proposed NHS Redress (Wales) Measure 2007 with Stage 2 amendments [http://www.assemblywales.org/proposed\\_nhs\\_redress\\_wales\\_measure\\_2007\\_as\\_amended\\_at\\_stage\\_2-e.pdf](http://www.assemblywales.org/proposed_nhs_redress_wales_measure_2007_as_amended_at_stage_2-e.pdf)

<sup>6</sup>Finance Committee, [Supplementary Report](#)

<sup>7</sup>Explanatory Memorandum with Stage 2 amendments [http://www.assemblywales.org/ms-ld6697-em\\_2\\_-e.pdf?langoption=3&ftl=MS-LD6697-EM%282%29%20-%20Explanatory%20Memorandum%20to%20the%20Proposed%20NHS%20Redress%20%28Wales%29%20Measure%202007](http://www.assemblywales.org/ms-ld6697-em_2_-e.pdf?langoption=3&ftl=MS-LD6697-EM%282%29%20-%20Explanatory%20Memorandum%20to%20the%20Proposed%20NHS%20Redress%20%28Wales%29%20Measure%202007)

<sup>8</sup>Proposed Measure Committee, Stage 2 Amendments, <http://www.assemblywales.org/bus-home/bus-legislation/bus-leg-measures/bus-legislative-meas-nhsrrev/bus-legislation-meas-nhsr-stage2.htm>

<sup>9</sup>Proposed Measure Committee, RoP Stage 2, Session 1, 4 March 2008, <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-nhsr-home/bus-committees-third-nhsr-agendas/nhs20080304fv.pdf?langoption=3&ftl=NHSR%283%29-02-08%20%3A%20Transcript%20%28PDF%2C%2054-7kb%29>

<sup>10</sup>Proposed Measure Committee, RoP Stage 2, Session 2, 11 March 2008, <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-nhsr-home/bus-committees-third-nhsr-agendas/nhs20080311fv.pdf?langoption=3&ftl=NHSR%283%29-03-08%20%3A%20Transcript%20%28PDF%2033kb%29>

## Section 5 Method of delivering redress

- Delete (2)(b): “for time limits and any extensions of them in relation to acceptance of an offer of compensation as redress under the regulations”.
- (3) insert (za): “make provision for time limits and any extensions of them in relation to-
  - (i) the conduct and completion of an investigation;
  - (ii) the making of an offer of redress; and
  - (iii) the acceptance of such an offer,under the regulations,”

The effect of these two amendments is to require that regulations made under section 5 of the Measure **must** provide for time limits in respect of the investigation and conclusion of cases being dealt with under the NHS redress arrangements. Previously, the Measure provided (at paragraph 5(2)(b)) that regulations made under this section only **may**, in particular, include provision for time limits. This is in line with the Stage 1 Committee’s recommendation at paragraph 114 of its report (see also paragraphs 98-103).

## Section 9 Functions with regard to redress arrangements

- (2) Delete the word “such” before “persons or bodies”
- (3) Amend sentence from “The regulations may require that, in carrying out functions under the regulations, any body or person to whom the regulations apply-“ to “The regulations may require any body or person carrying out functions under the regulations to-“
- (4) Amend sentence from “The regulations must require that a body or person to whom the regulations apply prepare and publish an annual report about cases involving that body or person that are dealt with under the regulations and the lessons to be learnt from them” to “The regulations must require that such a body or person prepare and publish an annual report about cases involving that body or person that are dealt with under the regulations and the lessons to be learnt from them”.
- (5) Add to end of sentence “to whom the regulations apply”.
- (7) After “body or person” delete “to whom the regulations apply”. After “provision of services” insert “shall”.

## Section 10 Complaints

- (d) After provision of redress, delete “arrangements”

## Section 11 Orders and regulations

- (6) Insert after (b):
  - “(c) contains regulations making provision under section 1(4)(b), section 1(5), section 3 or section 5, or
  - (d) contains the first regulations to make provision under sections, 2,4,6,7 or 9,”

The effect of this amendment is to extend the range of regulations that should be considered under the affirmative procedure to include those which specify a body or person other than a healthcare professional who is judged to have a qualifying liability in tort; the qualifying services to which the redress arrangements will apply; access to redress; and the delivery of redress arrangements. In addition, **the first set of regulations** relating to the form of redress that may be offered, duty to investigate claims of redress, suspension of the limitation period, provision of free legal advice and functions with regard to the operation of the arrangements must also be considered under the affirmative procedure. This amendment takes account of the findings of the Stage 1 Committee (see paragraphs 166-173 of the Stage 1 Committee report).

### 3 COMMITTEE STAGE 1 – PRE-LEGISLATIVE SCRUTINY

This section is in three parts:

- 3.1 Reproduction of the summary of recommendations from the Stage 1 Committee report
- 3.2 Recommendations from the Subordinate Legislation Committee
- 3.3 Considerations of the Finance Committee

### **3.1: SUMMARY OF RECOMMENDATIONS FROM THE STAGE 1 COMMITTEE REPORT**

#### **Committee approach**

1. Much of the evidence we received commented on some detailed issues relating to redress which are more relevant to the drafting of the regulations under the Measure and we would urge the Minister to take account of these when preparing regulations for consultation (paragraph 10).

#### **Lack of information**

2. There are still some areas where we are concerned about the lack of information we have had to support our consideration of the general principles and we identify these elsewhere in the report. We would expect the Minister to cover these specific areas in the Stage 1 debate so that all Assembly Members can reach an informed view on the general principles before the Measure is subject to more detailed scrutiny (paragraph 19).

#### **Framework nature of Measure**

3. We recognise that as the first Assembly Measure to have been scrutinised by a committee at Stage 1, the proposed NHS Redress Measure has attracted some criticism because of its framework nature. It is not unusual for legislation to confer regulation making powers on Ministers. However, we recommend that where future Measures take a similar approach in conferring wide regulation making powers to Welsh Ministers, they should be accompanied by a more detailed report on the policy behind the legislation to allow considered scrutiny by the Assembly. Furthermore, the policy should always have been developed before any proposed Measure is introduced into the Assembly (paragraph 31).

#### **Relationship of the redress arrangements with the complaints procedure**

4. We recommend that the Minister ensures there is complete clarity in the regulations as to how the complaints procedure and the Speedy Resolution Scheme will work alongside any redress arrangements (paragraph 42).

5. We recommend there should also be sufficient safeguards built into the redress arrangements to ensure that patients who do not receive a financial award do not feel that their complaint was any less valid than a patient who did (paragraph 43).

### **No fault schemes**

6. Given the evidence we have received in relation to no-fault based schemes we conclude that this should not be explored at present. A great deal of further work and investigation would need to be carried out before decisions were made on anything other than a tort based scheme of redress (paragraph 52). (*See Annex B of this paper for further information on existing no-fault schemes.*)

### **Scope of the redress scheme (Sections 1 & 2)**

#### *Inclusion of primary care under the redress scheme*

7. We recommend that before any decision is taken to expand the redress arrangements to include primary care a full evaluation is conducted of the scheme's operation in the secondary care setting. We also recommend that the Minister should carry out a full and thorough consultation with stakeholders on any proposed expansion of the scheme to include primary healthcare and that this should take place prior to the drafting of the relevant regulations (paragraph 71).

#### *Impact on health professionals*

8. We recommend the Minister considers this area carefully and ensures that sufficient safeguards are built into the arrangements to ensure that NHS staff have confidence in the systems and are protected from unintended consequences (paragraph 81).

#### *Compensation limits*

9. We consider that it is appropriate for the limits for compensation to be set in regulations rather than in the Measure to ensure there is flexibility in the scheme (paragraph 88).

10. We recommend the Minister considers in further detail the level of the upper limit for compensation and, in particular, the view put forward regarding the danger of setting too low a limit which could mean that some cases may fall outside the redress scheme, but

may not be eligible for public funding to take forward a case through the courts. The upper limit for compensation will impact on the type and number of cases which are eligible for redress arrangements and this is an area where we would expect the Minister to provide further information for the Stage 1 debate (paragraph 89).

### **Investigations under the scheme (Sections 4 & 5)**

11. The investigations process is key to the success of any redress arrangements and we urge the Minister to ensure that the detailed evidence we have received on the investigations process is taken into account by the working group and during the formulation of the relevant regulations (paragraph 113).

12. We consider that interim time limits are required to ensure that both patients and NHS staff have confidence in any redress arrangements. We consider that it is appropriate for these time limits to be set out in future regulations under the Measure. We recommend, however, that the Measure should be amended to require that regulations must make provision for time limits in relation to the investigations process (paragraph 114).

#### *Withholding of investigation reports*

13. We recommend that the Measure should be strengthened to prescribe that investigation reports will normally be disclosed and that they may only be withheld in exceptional circumstances. Safeguards should also be included in the Measure to ensure that any decision to withhold an investigation report should be reviewed by a body which is independent of the NHS organisation that is concerned in the case (paragraph 124).

#### *Duty to conduct inquiries*

14. We remain concerned about the lack of detail about how the provisions will operate and call for the Minister to make it clear in the regulations where the duty to conduct inquiries falls and how it will be enforced and monitored. We would expect the Minister to provide further information on this for the Stage 1 debate (paragraph 131).



### **Advice and assistance under the scheme (Sections 7 & 8)**

15. We recognise the importance of providing clear, consistent advice and information to patients under the redress arrangements and we welcome the commitment to provide advice and assistance free of charge as part of the redress scheme (paragraph 153).

16. We note the interim findings of the working groups on this issue and call for the Minister to provide further details on the operation of these provisions for the Stage 1 debate. In particular, we seek clarification from the Minister on when advice and assistance will be accessible under the scheme, who will provide such advice and assistance, and how these services will be monitored to ensure consistency of approach (paragraph 154).

### **Structure of the scheme (Section 9)**

17. We recommend that the regulations make provision for consistent management and guidance of the redress arrangements (paragraph 162).

### **Powers to make regulations (Section 11)**

18. We welcome the Minister's commitment to bring forward amendments at Stage 2 to tighten up the procedures for regulations made under the Measure and support the specific proposals outlined by the Subordinate Legislation Committee for a greater number of regulations to be subject to the affirmative procedure (paragraph 173).

#### *Duty to consult on regulations*

19. We recognise the Minister's commitment to consultation and the recommendations made by the Subordinate Legislation Committee. However, the evidence we received strongly supports the need for a statutory duty to consult on regulations and we recommend that given the wide regulation making powers this Measure confers on Welsh Ministers there should be a statutory duty to consult on all regulations subject to the affirmative procedure (paragraph 178).

## **Financial and resource considerations under the scheme**

20. We note the Finance Committee's recommendation that the Stage 1 debate should not take place before a more detailed assessment of the financial impact of the scheme has been provided by the Minister. We acknowledge the Finance Committee's concerns and recognise that it is important that any information which is laid in the Assembly accompanying a legislative proposal should be accurate and specific to Wales. We have received an assurance from the Minister that the necessary financial information will be provided for the Stage 1 debate (paragraph 191).

## **Conclusion**

21. The Committee welcomes this first proposed Assembly Measure and agrees unanimously to its general principles subject to the additional information set out in this report being presented by the Minister for the Stage 1 debate.

22. We recognise that the process taken for this first proposed Measure is not necessarily one that will set a precedent for future Measures. The proposed Measure is a product of the NHS Redress Act 2006 and, as such, much of the policy was still being developed while we were conducting our scrutiny work. This made it more difficult for stakeholders to come to a view on some of the general principles.

23. We are grateful to the Minister for the information provided by the Working Groups which has helped our consideration. We consider, however, that a substantial amount of detail still needs to be finalised before the regulations under the *Proposed Measure* can be prepared.

24. We expect future Measures to be handled differently. We consider that the policy behind a legislative proposal must be finalised before a proposed Measure is introduced for consideration by the Assembly. This will allow a greater degree of engagement with external stakeholders in terms of whether the legislation meets the policy objectives. It will also allow the relevant legislative committee to undertake proper and detailed scrutiny of the proposals (paragraphs 192-195).

### 3.2 SUBORDINATE LEGISLATION COMMITTEE RECOMMENDATIONS

The Subordinate Legislation Committee undertook a number of sessions scrutinising the *Proposed Measure* during September and October 2007 and its final report with the following recommendations was considered by them on 13 November 2007:<sup>11</sup>

#### *Recommendation (1)*

The Committee accepts that there are valid reasons why a 'Framework' Measure is justified in this case, but considers that the approach taken by this particular *Proposed Measure* should not set a precedent; and recommends that the Minister ensures that the level of scrutiny provided by the *Proposed Measure* in relation to different kinds of Regulations is as strong as possible.

#### *Recommendation (2)*

The Committee reserves the right to look again at this Measure when it is being considered at Stage 2.

#### *Recommendation (3)*

The Committee recommends that the first set of Regulations, which will set the scene for the foreseeable future, should follow the 'super affirmative' procedure; and subsequent Regulations should follow the procedures indicated in column 6 of the Table at Annex G.

#### *Recommendation (4)*

The Measure does not at present contain any specific duty to consult interested bodies in relation to any proposed Regulations. The Minister (see Annex C, Annex F paragraphs 5, 15, 23, 24 and 26 and Annex H) has assured the Committee that there will be full consultation before any Regulations are made. In relation to the inclusion of a duty to consult, the Committee accepts the Minister's assurances.

### 3.3 FINANCE COMMITTEE CONSIDERATIONS

The Finance Committee first looked at the financial implications of the *Proposed Measure* at its meeting on 20 September 2007<sup>12</sup> and produced an interim report for Stage 1, pending more robust information on the assessment of the cost of implementing the Proposed Measure from the Minister for Health and Social Services. The original financial impact assessment gave a wide-ranging estimate of costs. In giving evidence to

<sup>11</sup>Report on the Proposed NHS Redress (Wales) Measure 2007, 13 November 2007, <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-assem/bus-committees-third-sleg-home/bus-committees-third-sleg-agendas-2.htm?act=dis&id=65559&ds=11/2007>

the Proposed Measure Committee, Alun Cairns, AM expressed the view that while the Finance Committee would not be happy to complete Stage 1 unless the revised estimates were available, there was enough time for the Assembly Government to complete the work without putting the legislative timetable in jeopardy.

This information was duly received and at their meeting of 6 March 2008, members of the Finance Committee expressed satisfaction<sup>13</sup> that the more detailed information on costings they had requested had been received. Both the Final Assessment of the Financial Impact Assessment,<sup>14</sup> and the Interim Report containing a paper from the Minister in Annexes 2 (a) and (b) and 3,<sup>15</sup> are available on-line.

## 4 BACKGROUND INFORMATION

### 4.1 The Proposed NHS Redress (Wales) Measure 2007<sup>16</sup>

The *Proposed Measure* was introduced by the Minister for Health and Social Services on 3 July 2007. During the plenary debate that followed the Minister's announcement,<sup>17</sup> there was broad agreement from all Parties that the current system of NHS redress is flawed, complex, costly and adversarial and there was a need for the new legislation.

The *Proposed Measure* will give powers to Welsh Ministers to enable them to require providers or commissioners of services as part of the NHS in Wales to consider settling lower value clinical negligence claims without recourse to legal proceedings.

It is intended that this will be one part of a set of integrated arrangements, which includes the NHS complaints procedure, and the procedures for dealing with incidents. An important element of the *Proposed Measure* is that it also includes the requirement that **people using the redress arrangements should be entitled to receive legal advice and general support free of charge.**

The *Proposed Measure*, like the English *NHS Redress Act 2006*, is enabling but skeletal in nature, containing little detail and with much of the substance to be determined by **secondary legislation.**

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<sup>12</sup> Finance Committee, 20 September 2007, <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-assembus-committees-third-fin-home/bus-committees-third-fin-agendas.htm>

<sup>13</sup> Finance Committee, [Transcript](#), 6 March 2008

<sup>14</sup> Minister for Health and Social Services, [Final Assessment](#) of the Financial Impact Assessment, 21 February 2008

<sup>15</sup> Finance Committee, FIN(3) 05-08 (p3), 6 March 2008, <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-assembus-committees-third-fin-home/bus-committees-third-fin-agendas.htm?act=dis&id=77129&ds=3/2008>

<sup>16</sup> The *Proposed Measure* does not apply to primary care (i.e. primary dental, primary medical, general ophthalmic, and local pharmaceutical services), only to hospital and specialised commissioned care.

<sup>17</sup> Ibid. RoP, p37-61, 3 July 2007

Prior to the publication of the *Proposed Measure*, there was no formal consultation on the policy objectives or detail. However, formal consultation on the detail of the arrangements as set out in regulations is expected to take place during 2008 (EM 4.2)<sup>18</sup>. It was the intention that the affirmative procedure would be used the first time the regulations are made or when regulations **amend or repeal any Act of Parliament** with subsequent exercise of powers being subject to negative resolution procedure (EM 5.7). If primary care powers were sought in Wales, for example, those regulations would have been subject to the negative resolution procedure. However, during scrutiny, and in response to concerns that much of the detail would be made under regulations, the Minister agreed to any substantive regulations being considered by the Assembly (*see Stage 1 report, paragraphs 166-173 and Recommendation 1, paragraph 3.2 of this paper*) and subsequently amended the Measure at Stage 2.<sup>19</sup>

The *Proposed Measure* differs from the *NHS Redress Act 2006* in that the regulation making powers being sought are wide enough to apply to primary care, i.e. primary dental services, primary medical services, general ophthalmic services, and local pharmaceutical services, in addition to secondary care (hospital and specialised commissioned care). In England, the *2006 Act* does not contain powers for extending it to cover regulation of the primary care sector.

The *Proposed Measure* underwent **Committee Stage 1** during autumn 2007, and a draft report was circulated to Committee Members on 14 December 2007. The report was published on 25 January 2008<sup>20</sup> and was debated in Plenary on 29 January 2008<sup>21</sup> where it was agreed that the Measure could proceed to **Committee Stage 2**, completed on 11 March 2008.

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<sup>18</sup> Explanatory Memorandum, <http://www.assemblywales.org/ms-ld6697-em-e.pdf?langoption=3&ttl=MS-LD6697-EM%20-%20Explanatory%20Memorandum%20to%20the%20proposed%20NHS%20Redress%20%28Wales%29%20Measure%202007>

<sup>19</sup> Proposed NHS Redress (Wales) Measure Committee, [Stage 1 Report](#), 25 January 2008

<sup>20</sup> Ibid.

<sup>21</sup> RoP, p.47, NHS Redress Measure Committee Stage 1 Debate, 29 January 2008, <http://www.assemblywales.org/bus-home/bus-chamber/bus-chamber-third-assembly-rop/rop20080129qv.pdf?langoption=3&ttl=The%20Record%20%28PDF%2C%20572kb%29>

## 4.2 The Proposed NHS Redress (Wales) Measure 2007 Committee<sup>22</sup>

The *Proposed NHS Redress (Wales) Measure 2007 Committee* was established on 4 July 2007. At its first meeting on 12 July 2007, the Committee agreed to undertake a consultation over the summer period. The consultation letter<sup>23</sup> contained the scope of its pre-legislative scrutiny working within the framework of the following three general questions:

- Why is a Redress Scheme required?
- Does the *Proposed Measure* achieve the policy objective?
- What are the views of stakeholders who will have to work with a redress system?

The Committee also invited consultees to consider more detailed questions, specifically:

- What will be the practicalities of making the system work and does the *Proposed Measure* make provision for these?
- Is it appropriate that so much be done by regulations, i.e. the details of any scheme or schemes will be decided by Welsh Ministers?
- The Measure relates to redress in relation to liability in tort, i.e. where some fault is established without recourse to the courts. Would it be better for the Assembly to seek the power from Westminster to introduce a 'no-fault scheme'?

Thirty four responses to the consultation exercise were received, and further evidence was taken from 12 of the respondents during four oral sessions.<sup>24</sup> An analysis of the key themes that emerged from the written responses can be found at Annex A.

A fifth oral session, held on 6 November 2007, included evidence from Dai Lloyd, AM and Alun Cairns, AM, Chairs of the **Subordinate Legislation Committee** and the **Finance Committee** respectively, both of which undertook pre-legislative scrutiny of the *Proposed*

<sup>22</sup> Proposed NHS Redress (Wales) Measure 2007 Committee web-pages, <http://www.assemblywales.org/bus-home/bus-legislation/bus-leg-measures/bus-legislation-meas-nhsr.htm>

<sup>23</sup> [consultation letter](#)

<sup>24</sup> Proposed NHS Redress (Wales) Measure 2007 web-pages, <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-assembly/bus-committees-third-nhsr-home.htm>



*Measure.* Also giving evidence at the 6 November meeting was the Minister for Health and Social Services.

The *Proposed Measure* Committee finished taking evidence towards the end of the autumn term 2007, but delayed publishing the report until interim information from the Working Groups set up by the Minister on the progress of the Putting Things Right project was available in January 2008 (see *Annex E of the Stage 1 Report*). The Stage 1 Committee report was published at the end of January.<sup>25</sup>

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<sup>25</sup>[Stage 1 Report](#) from the Proposed NHS Redress (Wales) Committee, January 2008

## ANNEX A

### Consultation responses – key themes

Over 30 responses were received to the consultation. Most respondents welcomed the Measure and the introduction of redress arrangements within secondary care. There were significant reservations about extending the scheme to primary care.

#### ■ *Integrated service delivery*

There has been a policy drive for integrated delivery of seamless services within Wales. There needs to be clarity about how the *Proposed Measure* will work within an environment of integrated service delivery and a need to define when and where redress measures would and would not be applicable to avoid confusion.<sup>26 27</sup>

#### ■ *Lack of detail in the Measure and whether the Measure meets the policy objectives*

Because the Measure is enabling in nature with the detail coming via regulations, some respondents felt that they could not comment on whether the Measure will achieve the policy objectives and that it was therefore very difficult to make an objective assessment of the implications of the Measure.<sup>28 29 30 31 32 33 34 35</sup>

**Tomorrow's Wales** expressed 'considerable concerns' about the provisions and the extensive delegation of powers to Welsh ministers. They contend that the Measure should not be proceeded with and that the Assembly is being asked to agree to legislation without knowing how the Assembly Government proposes to implement the provisions.<sup>36</sup>

Tomorrow's Wales gave evidence to the Subordinate Legislation Committee on 25 September 2007.<sup>37</sup>

**The Law Society** comment that their major concern at this stage is that the *Proposed Measure* does not go into sufficient detail as to how the scheme will operate relegating all of the substantive provisions to subordinate legislation. They question whether it should

<sup>26</sup> NHSR2 - Caerphilly County Borough Council

<sup>27</sup> NHSR21 - Carmarthenshire County Council

<sup>28</sup> NHSR5 - BMA

<sup>29</sup> NHSR7 - Vale of Glamorgan LHB

<sup>30</sup> NHSR10 - Chartered Society of Physiotherapy

<sup>31</sup> NHSR11 - Legal Services Commission

<sup>32</sup> NHSR11 - Legal Services Commission

<sup>33</sup> NHSR17 - National Pharmacy Association

<sup>34</sup> NHSR25 - Medical Protection Society and Dental Protection Limited

<sup>35</sup> NHSR27 - Tim Musgrove

<sup>36</sup> NHSR8 - Tomorrow's Wales/Cymru Yfory

<sup>37</sup> National Assembly for Wales, Subordinate legislation Committee, 25 September 2007 <http://www.assemblywales.org/bus-home/bus-committees/bus-committees-third-assem/bus-committees-third-sleg-home/bus-committees-third-sleg-agendas-2.htm>



include much more detail as to how the scheme will actually operate and who will make particular decisions. They suggest that scrutiny of the Measure should await a full report of its policy from the Government, with evidence of stakeholder views as well as the full text of the proposed regulations so that the matter can be considered as a whole.<sup>38</sup>

■ *Primary care*

Several respondents argued that professional indemnity arrangements within primary care are different, already work effectively and that there is no reason to extend the scheme to primary care.

**The BMA** says that GPs should be excluded from the Measure.<sup>39</sup>

**Optometry Wales** sees no need for an NHS redress scheme to apply to community optometrists, and, by analogy, all contractors in primary health care, arguing that the current system of compensation is already working well and that enforcement in primary care would potentially undermine the current provision of professional indemnity insurance. The profession's insurers have advised that they would reconsider providing appropriate cover.

It is questioned whether WAG has consulted with the regulatory bodies on how the matter of Fitness to Practice within the current regime of regulation of the profession would continue to function if the no-fault principle is introduced.<sup>40</sup>

**Community Pharmacy Wales** shares this concern stating that a redress scheme for primary care is not required or justified at this time and that 'there are major issues of Clinical Governance and how the *Proposed Measure* ties in with professional performance, Fitness to Practice and other professional regulatory issues.<sup>41</sup> The **National Pharmacy Association**, the **Royal Pharmaceutical Society** and the **Medical Protection Society/Dental Protection Society** all concur that primary care contractors should be excluded.

The **Medical Defence Union** suggests that the redress scheme could operate for a trial period before being considered for primary care.<sup>42</sup>

■ *Provision of legal advice and advocacy*

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<sup>38</sup> NHSR31 - The Law Society

<sup>39</sup> NHSR5 - BMA

<sup>40</sup> NHSR6 - Optometry Wales

<sup>41</sup> NHSR4 - Community Pharmacy Wales

<sup>42</sup> NHS24 - Medical Defence Union

The **Legal Services Commission** (LSC) is concerned to ensure that claimants have access to quality assured legal advice. It is their view that any appropriate legal advice and representation needed within the scheme or by a client who has received an offer under the scheme should be provided for as an integrated part of the scheme itself.<sup>43</sup>

It is not clear which organisations would provide advice under Section 8 of the *Proposed Measure* ('Assistance for individuals seeking redress'). **Citizens Advice Cymru** (CAB) comments that if it is the assumption that Community Health Councils would do this, then there is potential for the CAB network to offer some holistic advice package in conjunction with them.<sup>44</sup>

**CAB** question how easy it will be to obtain advice before starting the formal redress route, suggesting that Section 7 (2) could also include the provision of free legal advice as to whether to make a claim (in addition to what is set out in the Measure i.e. free legal advice in relation to 'any offer that is made', 'any refusal to make such an offer' and 'any settlement agreement').<sup>45</sup>

More clarity is needed on the role of independent advice under the Measure. This could be achieved by setting out in the Measure, rather than in the regulations, a commitment to provide funding or the structure of the funding arrangements.<sup>46</sup> The **LSC** is concerned if it is proposed that all advice could be given by or on behalf of the NHS<sup>47</sup> and the Board of Community Health Councils say that confidence will only be gained through independent support and advice for the complaint.<sup>48</sup>

**WCVA** express 'great concern' that it is not considered that the Measure will have any impact on the voluntary sector as set out in the Explanatory Memorandum (para 8 and 9). WCVA argue there will be a significant impact on a wide range of independent advocacy advice and support services. Whilst support may come from Community Health Councils, they are unlikely to be equipped to deal with the most vulnerable so there should be a detailed assessment made of the impact on independent advocacy services.<sup>49</sup>

#### ■ *Cost of legal advice*

The specific cost of providing legal advice is not considered in the Explanatory Memorandum. **The Law Society** states that if it is the intention that the funding of legal

<sup>43</sup> NHSR11 - Legal Services Commission

<sup>44</sup> NHSR3 - Citizens Advice Cymru para 2.7

<sup>45</sup> NHSR3 - Citizens Advice Cymru para 2.5 and 3.2

<sup>46</sup> NHSR11 - Legal Services Commission

<sup>47</sup> NHSR11 - Legal Services Commission

<sup>48</sup> NHSR20 - Board of Community Health Councils

advice under the scheme will be available from the Legal Services Commission, a full assessment should be undertaken to ascertain the extent of the effect on the fund, and, if this is in excess of the current spend on clinical negligence, annual reimbursement should be made to the legal aid fund.<sup>50</sup>

■ *Time Limits*

**The Law Society** states that as currently drafted, the Measure does not provide for time limits for proceedings to be commenced or concluded and that it should specifically provide for a time limit to be imposed for the conclusion of proceedings commenced under the scheme.<sup>51</sup>

■ *Mental health*

**Hafal** calls for there to be a commitment in the Measure that there will be no exclusions or qualifications of the application of the Measure to mental health. It also calls for the Measure to require regulations to include specific actions to support people with mental illness.<sup>52</sup>

**Bridgend Borough Council** asks whether the interpretation of 'Health Care Professional' (section 13 of the Measure) will include a social worker working in mental health and whether new Approved Workers will fall within the redress arrangements or within local authority arrangements.<sup>53</sup>

■ *No-fault schemes*

There was a mix of views about whether the Assembly should seek further powers to introduce a no-fault scheme. Many respondents commented that there should be further investigation into such schemes. The **Medical Defence Union** in particular, gives some detail on the issue of liability in tort and no-fault schemes. (Also, see Annex B below for some background briefing on this).

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<sup>49</sup> NHSR12 - WCVA

<sup>50</sup> NHSR31 - The Law Society

<sup>51</sup> NHSR31 - The Law Society

<sup>52</sup> NHSR22 - Hafal

<sup>53</sup> MHSR11 - Bridgend Borough Council

## ANNEX B

### Experience of no-fault schemes elsewhere

#### *New Zealand*

The first country to introduce a no-fault compensation system was New Zealand in 1972. The no-fault system replaced the tort system but in 1992 a reformed Act was passed to address some of the criticisms made of the original legislation. The criticisms centred on compensation shortfalls, lack of accountability of doctors and the definition of medical misadventure (used in place of medical negligence). The reformed Act addressed some of the issues and 'laid heavy emphasis on disciplining doctors at fault'. Although the system appears to work well in the field of medical litigation, its minimal cover and complete bar on the right to sue remain unique to New Zealand.

The New Zealand scheme operates as part of a wider no-fault compensation scheme, which includes work-related and traffic accident sustained injuries. In terms of medical negligence, it compensates for injuries that result from error by medical practitioners or from rare and severe outcomes of medical or surgical procedures.<sup>54</sup>

In 2005 New South Wales parliamentary briefing paper, which discussed and compared various schemes, stated in relation to the New Zealand system:<sup>55</sup>

In return for no-fault cover, individuals forego the right to sue for personal injury. However, whilst injured persons in New Zealand are precluded from suing for personal injury, they retain the right to sue for exemplary damages. Exemplary damages are not awarded as compensation. They are usually ordered as a form of punishment where the court believes the defendant acted in complete disregard for the rights of the plaintiff, or if the court feels a need to impose them to deter others from such conduct.

In their evidence to the NHS Redress Measure Committee, the Medical Protection Society and Dental Protection Limited state that they have found that the no-fault scheme has undermined morale in the medical profession, increased the number of disciplinary proceedings and dented public confidence in the healthcare system. In addition no-fault systems are open to the risk of abuse.

#### *Scandinavia*

Two systems operate in Scandinavia. Denmark and Finland have adopted mandatory patients' insurance schemes, while Sweden and Norway introduced voluntary agreement insurance schemes based on a no-fault medical harm principle in 1975 and 1988 respectively.

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<sup>54</sup> New South Wales Parliament, Briefing Paper no 06/05, *No Fault Compensation*, May 2005, p.35  
[http://www.parliament.nsw.gov.au/prod/parliament/publications.nsf/0/54b0d80e7b70c457ca256ff9000dc9da:\\$FILE/No%20Fault%20Comp%20and%20Index.pdf](http://www.parliament.nsw.gov.au/prod/parliament/publications.nsf/0/54b0d80e7b70c457ca256ff9000dc9da:$FILE/No%20Fault%20Comp%20and%20Index.pdf)

<sup>55</sup> Ibid. p.35



In Sweden, the patient has to prove that the medical intervention caused the harm, and that either the treatment should not have been used, as it was inappropriate, or that, even if it was appropriate, the harm suffered by the patient was avoidable. Thus, if some side-effects of treatment are considered unavoidable, for example hair loss during chemotherapy, then there is no compensation payable.<sup>56</sup>

### ***France***

A different system exists in France where medical negligence claims against the state are handled under an administrative law scheme, separate from the civil justice system and compensation for hospital mistakes is automatic.<sup>57</sup> It is administered by the National Office of Medical Accident Compensation which was established in October 2002 to pay compensation in relation to medical accidents, problems resulting from an intervention by a medical practitioner and infection occurring during the course of treatment.

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<sup>56</sup> <http://www.scotconsumer.org.uk/publications/responses/resp06/re08faul.pdf>

<sup>57</sup> British Medical Journal, 10 May 2003; 326:997-998, *No-fault compensation systems*, <http://www.bmj.com/cgi/content/full/326/7397/997>