

Explanatory Memorandum to

The Digital Health and Care Wales (Establishment and Membership) Order 2020

And

The Digital Health and Care Wales (Membership and Procedure) Regulations 2020

This Explanatory Memorandum has been prepared by the Department for Health and Social Services and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the **Digital Health and Care Wales (Establishment and Membership) Order 2020** and **The Digital Health and Care Wales (Membership and Procedure) Regulations 2020**.

I am satisfied that the benefits justify the likely costs.

Vaughan Gething

Minister for Health and Social Services

9 December 2020

1. Description

1.1 The Legislation summarised below will establish a new Special Health Authority called Digital health and Care Wales.

a. The Digital Health and Care Wales (Establishment and Membership) Order 2020 ('the Order')

1.2 The order provides for the establishment of Digital Health and Care Wales ('DHCW') and makes provision about its constitution and overarching functions.

b. The Digital Health and Care Wales (Membership and Procedure) Regulations 2020

1.3 The Regulations supplement the Order and make detailed provision about the membership and procedures of DHCW. They provide for the appointment, eligibility and disqualification of members and DHCW's meetings, proceedings and committees.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2.1 The two statutory instruments being brought forward to establish DHCW are being made together, are inextricably linked, and would be difficult to understand if read in isolation. It is therefore considered beneficial to bring forward a single composite Explanatory Memorandum and Regulatory Impact Assessment.

3. Legislative background

3.1 The Welsh Ministers have powers in section 22 of the National Health Service (Wales) Act 2006 ('the 2006 Act') to establish a Special Health Authority for the purpose of exercising any functions which may be conferred on them by or under the 2006 Act. The power is exercisable by order. Under section 24 of the 2006 Act the Welsh Ministers may direct a Special Health Authority to exercise functions of the Welsh Ministers relating to the health service. The Welsh Ministers may also, under section 23, give directions to a Special Health Authority about its exercise of any functions, save in respect the matters which are specifically reserved in section 23(2)¹.

3.2 Under powers conferred by Schedule 5 to the 2006 Act, the Welsh Ministers have the power to make regulations in respect of the members and officers of a Special Health Authority. They may also make provision in relation to matters such as the appointment and tenure of members,

¹ Section 23(2) provides that the Welsh Ministers may not give directions in respect of matters concerning xenotransplantation, surrogacy agreements, embryology or human genetics, which are not relevant here.

the appointment of committees, the procedures of the Authority and other matters.

4. Purpose & intended effect of the legislation

Background

- 4.1 The NHS Wales Informatics Service ('NWIS') is the organisation leading on the delivery of national digital health and care services for NHS Wales. Established on 1 April 2010 (as part of the NHS Wales Healthcare Reform Programme) it brought together:
- Informing Healthcare (IHC),
 - Health Solutions Wales (HSW),
 - Business Services Centre (Information Management and Technology element only),
 - Corporate Health Information Programme (CHIP), and the
 - Primary Care Informatics Programme (PCIP).
- 4.2 NWIS is a non-statutory organisation, hosted under the statutory framework of Velindre NHS Trust. It has its own Directors and Corporate Structure, with staff located across Wales.

Purpose

- 4.3 In 2019, Welsh Government commissioned two major reviews of digital delivery in Wales looking at how digital systems are designed to work together ('the Digital Architecture Review') and at delivery structures and decision-making arrangements ('the Digital Governance Review'). These two reviews provide the context to our approach and delivery.
- 4.4 Given the sensitivity of the recommendations raised by the 'Digital Governance Review', officials developed options based on the general engagement undertaken by both reviews, including the stakeholder task and finish groups, on consideration of existing governance and hosting models across NHS Wales (which provide several examples of different approaches), and discussions with the Minister.
- 4.5 In a written statement on 30 September 2019, the Minister for Health and Social Services announced:

"The NHS Wales Informatics Service (NWIS) will transition from its current structure, as part of Velindre Trust, to a new Special Health Authority. Establishing our national digital services organisation as a dedicated organisation reflects the importance of digital technology as a key enabler of change, as set out in A Healthier Wales. This change will strengthen governance and accountability, both in terms of relationships with other NHS Wales organisations and through stronger leadership and oversight, through an

independent chair and board members, with experience and understanding of digital change.”

- 4.6 Bringing into force the legislation listed above is the first step towards achieving the commitment made by the Minister. The legislation will establish DHCW, make provision as to its membership to enable it to undertake the work necessary in advance of the body becoming operational later in 2021.

Intended effect of the legislation

The Digital Health and Care Wales (Establishment and Membership) Order 2020

- 4.7 The Order makes provision for the establishment of DHCW and provides for the membership of the new body. It also confirms that DHCW is to exercise functions as directed by the Welsh Ministers in connection with the matters set out within the Order, including in relation to the design, development and delivery of digital platforms, services and systems for the Health and Care Sector in Wales. The Welsh Ministers also have the power to direct DHCW as to the exercise of any functions.
- 4.8 DHCW will be a new organisation within NHS Wales, sitting alongside the current seven Health Boards, three NHS Trusts and a single Special Health Authority (Health Education Improvement Wales – HEIW); with the overarching responsibility for providing a source for Digital platforms, services and systems for the Health and Care Sector in Wales.

The Digital Health and Care Wales (Membership and Procedure) Regulations 2020

- 4.9 The Board will comprise of a minimum of six members and may be comprised of up to fifteen members in total, split between independent, officer members and ex-officio (associate) members. The number of officer members may not exceed the number of non-officer members. There will be at least three officer members, which will include within that number a Chief Officer.
- 4.10 The Membership Regulations will set out procedural matters and detail in relation to the various members, including their appointment, eligibility, tenure, disqualification, suspension and removal from office. In addition, the Regulations require DHCW to make standing orders regarding its meetings and proceedings. They also set out requirements in relation to the appointment of and exercise of functions by committees and provide powers to the vice-chair in the event of the Chair being unavailable, so that DHCW may continue to operate effectively. Lastly, the Regulations also set out duties in relation to reporting.

- 4.11 In relation to the Chief Officer, the Welsh Ministers will make the first appointment, with subsequent appointments being made by the independent (non-officer) members. Specific provision is also made in the Regulations as to how the other members are to be appointed.
- 4.12 The Order and Membership Regulations provide the legal framework for the establishment of Digital Health and Care Wales.

5. Consultation and Regulatory Impact Assessment (RIA)

- 5.1 Between 7 September 2020 and 30 November 2020, Welsh Government sought views from stakeholders on the proposed functions of a new Special Health Authority called Digital Health and Care Wales (DHCW).
- 5.2 The consultation described why Welsh Government are proposing the change; the proposed functions currently being undertaken by NHS Wales Informatics Service (NWIS) that will be taken forward by DHCW; and how these functions can facilitate the evolution of digital maturity across the health and care sector in Wales.
- 5.3 The consultation requested views on the following areas and stakeholders were asked to submit their comments via an online form, email or post.
- The proposed functions of DHCW.
 - The proposed board structure for DHCW.
 - Whether one or more of the proposed functions of DHCW overlaps with a function already being undertaken by a different organisation in Wales (that is not NWIS).
 - Additional functions that should be included within the responsibility of DHCW.
 - Any impacts the proposed functions may have on the Welsh language.

6. General overview of the consultation responses.

- 6.1 There were a total of seventy seven responses to the consultation. Some of the written responses reflected the consolidated views of organisations within NHS Wales.
- 6.2 In general, responses tended to elicit comments from respondents which were broadly supportive of the proposals. The open nature of the consultation form meant many provided additional information, added caveats or raised issues for further consideration. These were varied and, in many cases, were specific to the respondent and/or the organisation that they represented.
- 6.3 Some cross-cutting issues included the need to integrate any changes in the context of the current policy landscape and with regard to existing

structures, as well as to learn from and use the experience of existing bodies and programmes and the need to share best practice.

- 6.4 The consultation focussed on the proposed functions of DHCW, however, some respondents highlighted operational concerns for the new organisation which do not directly correlate to the functions Welsh Government propose to confer on DHCW. Where this is the case these concerns will be highlighted for consideration by the DHCW board once appointed.

PART 2 – REGULATORY IMPACT ASSESSMENT

7. Options

- 7.1 The Welsh Government considered a number of options in response to the recommendations made in the ‘the Digital Architecture Review’ and ‘the Digital Governance Review’. These options were:
1. Do Nothing
 2. No change of structure, but add a ‘joint committee’ governance wrapper around NWIS in Velindre
 3. Move NWIS to another organisation such as Public Health Wales, HEIW or the NHS Executive
 4. Transition NWIS to a new standalone Special Health Authority
- 7.2 An assessment was made of the extent to which each of these options delivers the recommendations made in the two commissioned reports.

Option 1 – Do Nothing

- 7.3 This option would not address any of the recommendations from the Wales Audit Office (WAO) and Public Accounts Committee (PAC) reports or the Governance Review. Pursuing this option would further undermine confidence and engagement across NHS Wales and could have a detrimental impact on the reputation of Welsh Ministers and the ability to deliver/develop national digital systems and services.
- 7.4 This option was therefore rejected but is retained in the RIA to act as the baseline against which to assess the costs and benefits of the alternative options.

Option 2 – No change of structure, but add a ‘joint committee’ governance wrapper around NWIS in Velindre

- 7.5 While this option would address some of the recommendations from the WAO and PAC reports around governance and accountability and would move towards a ‘shared services’ model as described in the governance review, it was felt this option would maintain the currently ambiguous hosting arrangements, lack financial accountability and would be seen as a largely ‘cosmetic’ change. For these reasons, this option was rejected.

Option 3 – Move NWIS to another organisation such as Public Health Wales, HEIW or the NHS Executive

- 7.6 This option would go further than options 1 and 2 in addressing the recommendations by the WAO and PAC, showing ‘significant’ change. However, this approach stops short of addressing the key governance changes required. There would however be some disruption in transitioning from Velindre to a different organisation with different processes and requirements, even within the wider NHS Wales system.

Given the scale of NWIS there could also be an impact on the receiving organisation which could distract senior leadership from their existing priorities and focus. As a result, this option was rejected.

Option 4: Transition NWIS to a new standalone Special Health Authority

- 7.7 This option was felt to address the WAO and PAC recommendations to their fullest extent, and to maximise the direct and transparent accountability of NWIS as a national digital service. As such, this option was identified as the preferred option.
- 7.8 In September 2019, the Minister for Health and Social Services announced his intention to transition the NHS Wales Information Service (NWIS) into a Special Health Authority.
- 7.9 In light of the above, the following options have been taken forward for further consideration in the RIA:
- Option 1 – Do Nothing
 - Option 4 - Transition NWIS to a new standalone Special Health Authority

8. Costs

Option 1 – Do Nothing

Costs

- 8.1 This is the baseline option and as such, there are no additional costs associated with this option.

Benefits

- 8.2 Given that current systems would continue, there would be no benefits to this option in terms of value for money against the investment made into this area of the system. However, there would be a benefit in that no additional establishment or transitional costs would be required. There would be no policy benefit in relation to digital services across the NHS in Wales. There could however, be an unquantifiable potential benefit for the staff involved, in that they would continue within their current roles, organisations and locations.

Option 4 - Transition NWIS to a new standalone Special Health Authority

Costs

- 8.3 This option is likely to require more resources than options 1, 2 and 3, although the task is relatively straightforward (compared for example to establishing HEIW) because NWIS is an established organisation with existing people, premises, processes and policies.

8.4 There would also be costs associated with transitioning NWIS into a 'clean' SHA and establishing a new Board. The costs for Board membership may decrease if less time is required per month.

8.5 The costs to "Transition NWIS to a new standalone Special Health Authority" will mainly be incurred in the 2020-21 financial year. However, some costs may flow into 2021-22 to support programme closure activity.

Resource	Description	Cost
Programme Team	Costs for Programme Team <i>Staff costs incurred by Welsh Government to deliver the programme.</i>	£160,000
Legal	Costs for Legal Advice and Legislative Drafting <i>Legal costs incurred by Welsh Government to provide legal advice and drafting of legislation.</i>	£20,000
Communications and Engagement	Costs for Communications and Engagement Activities <i>Wider communication and engagement activities to support the programme.</i>	£10,000
People	Non-Officer Member costs. <i>Remuneration and associated costs for a Chair, Vice Chair and Five independent members.</i>	£126,500
Other Costs	Other Ad hoc programme costs (such as Gateway Reviews etc.).	£20,000
Transition Costs	See Appendix B for details	£717,800
	Total	£1,054,300

Benefits

8.6 There are some short-term benefits linked to the governance and transparency of establishing the new SHA, which are set out below:

- a. An independent organisation allows a dedicated chair and board exclusively focussed on digital delivery, and would help to emphasise the importance of digital services alongside other key enablers such as education.
- b. By establishing a Special Health Authority, it will help improve the transparency, reporting and accountability of digital services within NHS Wales through a formalised governance framework.

- c. This would move the national digital service in Wales to a similar status as other parts of the UK (for example England's NHS Digital is constituted as an arms-length public body), and would be seen as a 'significant' change.
- 8.7 The full benefits of the Programme will be realised in the long term and will continue over a sustained period. Benefits that relate to the functions of the new organisation will be captured Regulatory Impact Assessment that accompanies the associated legislation leading up to 1 April 2021.
- 8.8 Longer term benefits the new organisation will provide across the system in Wales will be identified and addressed by the Board of the new organisation as part of their business and IMTP plans.

9. Summary

- 9.1 Option 4 provides opportunities for a clean break, which allows addressing the recommendations of the Wales Audit Office and Public Accounts Committee to the fullest, without negatively affecting the digital services provided to professionals and patients.
- 9.2 Aligning the Special Health Authority to a new formalised governance framework will not just improve transparency, reporting and accountability of digital services within NWIS Wales but will also provide much needed confidence across the system that the changes undertaken are substantial in nature and not just cosmetic.

10. Consultation

Wales Audit Office Review - Informatics Systems in NHS Wales – 10 January 2018

- 10.1 Work to develop policy in this area started in 2018 when the Wales Audit Officer (now Audit Wales) commissioned a review into Informatics Systems in NHS Wales. Whilst compiling their report, the WAO interviewed a range of people including Welsh Government officials, NWIS Staff and a range of officers from Health Boards and Trusts.

The Parliamentary Review of Health and Social Care in Wales – January 2018

- 10.2 The Parliamentary Review of Health and Social Care in Wales was undertaken in January 2018. In formulating their views, the Parliamentary Review heard from a wide range of people including members of the public, service users, staff in health and social care, and the third sector, and considered evidence about national and international models of care.

Public Accounts Committee Report – November 2018

- 10.3 Based on the recommendations set out in the Wales Audit Officer and Parliamentary Review, the Public Accounts Committee agreed to undertake an inquiry into informatics systems in NHS Wales, covering a wide range of issues. The Committee received extensive written and oral evidence as part of their inquiry. There have been a number of Public Accounts Committee Evidence Sessions to date and the transcripts of all oral evidence sessions and written evidence received are openly available².

The NHS Wales Digital Architecture Review

- 10.4 Welsh Government and NHS Wales engaged Channel 3 Consulting to undertake a review of the NHS Wales Digital Architecture, recognising the ambition for digital transformation across Wales at pace.
- 10.5 The focus of this review was to assess the extent to which the current Digital Architecture of NHS Wales is ready to meet the ambition set out in “A Healthier Wales”, and whether it is scalable to support digital transformation across Welsh health and social care.
- 10.6 The review involved technical reviews with NWIS and workshops and interviews with over one hundred key stakeholders from NWIS, all Health Boards, and the universities, augmented by three “deep dives” at Aneurin Bevan and Cwm Taf Health Boards, and Public Health Wales Trust.

The NHS Wales Digital Governance Review

- 10.7 The review had a whole system scope, covering local and national services, all NHS services, and the Welsh Community Care Information System (WCCIS) and undertaken by independent consultants, who engaged very widely with all stakeholders across Wales, including NHS Wales Informatics Service (NWIS) and Velindre NHS Trust.
- 10.8 The Review engaged widely with stakeholders on an open and collaborative basis. The findings and recommendations from the Review have been widely shared with NHS Wales Stakeholders through an engagement programme.
- 10.9 The Digital Governance Review found that there was widespread support for change across NHS Wales.

The Ministerial Written Statement – 30 September 2019

² <http://senedd.assembly.wales/mgIssueHistoryHome.aspx?IId=20803>

- 10.10 In his written statement, the Minister for Health and Social Services set out actions in response to the two reviews, which has been widely reported announcing that:

“The NHS Wales Informatics Service (NWIS) will transition from its current structure, as part of Velindre Trust, to a new Special Health Authority. Establishing our national digital services organisation as a dedicated organisation reflects the importance of digital technology as a key enabler of change, as set out in A Healthier Wales. This change will strengthen governance and accountability, both in terms of relationships with other NHS Wales organisations and through stronger leadership and oversight, through an independent chair and board members, with experience and understanding of digital change.”

- 10.11 The Minister for Health and Social Services also agreed there should be a new set of arrangements for Wales in regards to delivering informatics and Digital transformation. This will help underpin key commitments published by Welsh Government such as *A Healthier Wales* and *Informed Health and Care Strategy*. Officials therefore consider there is a mandate for this change

External Consultation

- 10.12 Welsh Government published a consultation on the functions of the Digital Special Health Authority for Wales on 7 September 2020 and ran for twelve weeks, closing on 30 November 2020.

- 10.13 The high level functions subject to consultation were as follows:

- Application Development and Support
- Digital Services design, commissioning, planning & delivery
- Information and Communications Technology
- Quality Management & Regulatory Compliance
- Information Management
- Information Governance
- Cyber Security
- Finance and Business Assurance
- Reporting Services
- Workforce Improvement

- 10.14 Overall, the consultation responses welcomed the establishment of DHCW and were very supportive of the proposals.

11. Competition Assessment

- 11.1 The competition assessment has been completed and is included at Appendix A.

12. Post implementation review

- 12.1 The RIA sets out the anticipated potential costs of this legislation, in addition to the benefits and opportunities and realising these benefits is how success will be measured.
- 12.2 It is anticipated that a review will take place within five years of the full implementation of this legislation; with a further review at the ten year point, whereby the longer term benefits will have had the opportunity to be realised.
- 12.3 The key factors in measuring whether those benefits have been realised are as follows:
- A reduction in vacancies across the digital workforce across NHS Wales.
 - A reduction in skills gaps across digital professions.
 - Improved satisfaction ratings from patients and health care professionals through the national survey.
 - Improved staff survey results in relation to digital platforms, systems and services.
 - Improved value for investment, measured by an increase in outputs and/or service provision for similar investment against that made under the current system.
 - A reduction in consultancy and contractor spend on digital activity across the NHS in Wales.

APPENDIX A –The Competition Assessment

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

APPENDIX B – Detailed Transitional Costs

Transition Costs		
Resource	Description	Option 4
Communications and Engagement	Covering the branding and messaging for Digital Health and Care Wales as well as launch events and ancillary marketing activities.	£54,000
Statutory Financial Services Readiness	Ensuring the appropriate financial controls, processes and reporting procedures are in place and tested prior to 1 April 2021 go-live date. This includes key staff costs as well as supplier costs associated with the building of the organisation's Financial ledger and purchase of capital asset register for the new organisation.	£247,700
Workforce and Organisational Development Readiness	Supplier costs relating to the setting up of new ESR and expenses systems for the organisation in readiness for the go-live date.	£57,400
Governance Readiness	Supporting the ongoing development of the Board and Governance processes for Digital Health and Care Wales, this includes consultancy costs as well as staffing costs for the transition project manager, Board Secretary and Chair and Independent Members (following their appointment by Welsh Government).	£312,200
Legal Preparation	Legal advice to support the commercial activities relating to the transition such as the novation of contracts from Velindre to the SHA, Employment Law advice relating to the TUPE transfer and the setting up of employment licences and general legal advice relating to the creation of the Statutory Instruments to establish the SHA	£46,500
	Total:	£717,800