

EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE INFORMATION CENTRE (TRANSFER OF FUNCTIONS, ABOLITION AND TRANSITIONAL PROVISIONS) REGULATIONS 2023

2023 No. XXXX

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 This instrument abolishes the Health and Social Care Information Centre (**NHS Digital**) and transfers its statutory functions to NHS England. It does this by making amendments to various items of primary and secondary legislation. It also makes transitional and savings provision. This transfer is in response to the recommendations of the Laura Wade-Gery review: *Putting data, digital and tech at the heart of transforming the NHS*¹ (November, 2021).

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 This instrument will come into force the day after it is made. This is so that the transfer of responsibilities and staff can take place without any delay, providing certainty for staff, and to ensure continuity for essential systems such as IT platforms and databases on which the NHS relies.
- 3.2 The instrument does not create criminal offences or diminish the legal rights of any person. The instrument does not create significantly more onerous duties; rather it transfers existing functions between public bodies. Both NHS Digital and NHS England have been consulted on the policy and on the instrument and have had adequate time and opportunity to prepare for the change.

4. Extent and Territorial Application

- 4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England, Wales, Scotland and Northern Ireland.
- 4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England, Wales, Scotland and Northern Ireland.

5. European Convention on Human Rights

- 5.1 Lord Markham, the Parliamentary Under-Secretary of State, has made the following statement regarding Human Rights:

¹ <https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs>

“In my view the provisions of the Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 are compatible with the Convention rights.”

6. Legislative Context

- 6.1 The Health and Social Care Information Centre, also known as NHS Digital, was established by Part 9 of the Health and Social Care Act 2012 (**the 2012 Act**). The framework contained in the 2012 Act sets out NHS Digital’s functions in relation to the collection and analysis of information from, and the sharing of information by, health and adult social care commissioners and providers for the purposes of the health and social care system. NHS Digital has a number of additional duties and functions set out in other legislation.
- 6.2 Section 103(1) of the Health and Care Act 2022 (**the 2022 Act**) introduced a power for the Secretary of State to make regulations transferring the functions of certain non-departmental public bodies to others. Section 102 lists the bodies to which section 103 applies; the list includes NHS Digital and NHS England. This instrument abolishes NHS Digital and effects a transfer of its functions to NHS England.
- 6.3 It was not considered necessary to amend the constitution of NHS England in light of section 103(5) before making this instrument. This is because the statutory requirements relating to membership of NHS Digital do not include a requirement for it to include a member whose experience, functions or appointment are connected with a particular part of the United Kingdom.
- 6.4 The instrument makes consequential amendments to the Health and Social Care Act 2012 and to other relevant primary and secondary legislation. It also makes transitional provision in relation to things done by or in relation to NHS Digital before the transfer and provides for these to be treated as done by or in relation to NHS England. This means, for example, that directions given by the Secretary of State to NHS Digital before the transfer would be treated as given by the Secretary of State to NHS England (and NHS England must comply). The instrument also provides for directions given by NHS England to NHS Digital under the 2012 Act before the transfer to be treated as given by the Secretary of State to NHS England (and NHS England must comply). The instrument requires NHS England to prepare final accounts for NHS Digital and a final report on its exercise of functions.
- 6.5 The instrument also introduces additional safeguards requiring NHS England to report on how effectively it has discharged its relevant data functions and conferring a duty on the Secretary of State to issue guidance to which NHS England must have regard.

7. Policy background

What is being done and why?

- 7.1 Data powers our NHS and is key to understanding and improving our services. It can help to drive innovation and highlight where support can reduce inequalities and improve patient outcomes.
- 7.2 This transfer forms part of legislative reforms intended to strengthen the use of data to support delivery in the health and adult social care sectors, for the direct benefit of those being cared for and for the wider efficiency and development of the sector as a whole through the centralising of responsibilities for digital transformation.

- 7.3 The transfer of NHS Digital's functions follows a recommendation in Laura Wade-Gery's review *Putting data, digital and tech at the heart of transforming the NHS*² (November, 2021) (**the review**), which called for a realignment of the organisational responsibilities for digital transformation of the NHS to ensure delivery of a new operating model. The Secretary of State for Health and Social Care announced on publication of the review that NHS Digital's functions would be transferred to NHS England as soon as legislation allowed.
- 7.4 This transfer will reduce duplication of work, bringing the NHS' national data and technology expertise together into one organisation. There will no longer be several organisations responsible for different elements of the digital systems which support the NHS. It will also enable a closer link between the collection of data, and analysis of data and the delivery of service improvements. As a result of the transfer, a single body will be responsible for the data collated from the NHS and the delivery of NHS services.

Explanations

What did any law do before the changes to be made by this instrument?

- 7.5 Section 252 of the Health and Social Care Act 2012 established NHS Digital to carry out the collection and analysis of data generated from the provision of NHS and social care services. Directions can currently be given by the Secretary of State or NHS England to NHS Digital to establish and operate a system for the collection or analysis of information; similarly, a request could be made to NHS Digital to establish such a system. NHS Digital also exercises system delivery functions pursuant to directions given by the Secretary of State under regulation 32 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013. NHS Digital may also have functions conferred on it by regulations under section 2 of the Access to Medical Treatments (Innovation) Act 2016 and sections 7A or 19 of the Medicines and Medical Devices Act 2021. NHS Digital also has functions under regulations 15 and 16 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 and is also referred to in numerous other items of primary and secondary legislation.

Why is it being changed?

- 7.6 The review: *Putting data, digital and tech at the heart of transforming the NHS*³ highlighted a number of challenges facing the NHS. There is evidence that the separation of data functions (in NHS Digital) from NHS England's delivery function has caused challenges in that delivery did not always have the evidence needed for either planning or performance management. Similarly, leadership of digital transformation has been disjointed, with the former NHSX (a joint unit of DHSC and NHS England) and NHS Digital both having responsibility in addition to NHS England. The review concluded that the fragmentation of national bodies had made it hard to achieve the goal of a digitally enabled health system. A key recommendation, therefore, which this instrument aims to implement, was a realignment of the organisational responsibilities for digital transformation, embedding NHS Digital into

² <https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs>

³ <https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs>

NHS England as its “tech” function and as the NHS centre of excellence that makes use of modern technology and data-sharing to create joined-up services to support all citizens and improve outcomes. Following the publication of the review, the Secretary of State announced that the functions of NHS Digital would move to NHS England and that NHS Digital would be abolished, subject to parliamentary approval. This will bring together and centralise all of the bodies with national responsibilities for digital transformation, national IT and data services and delivery within a single organisation (NHS England), thereby creating a clear, central governance structure. [Putting data, digital and tech at the heart of transforming the NHS - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs)⁴

- 7.7 Therefore, the transfer of NHS Digital’s functions to NHS England and the winding up of NHS Digital has two objectives: to bring data and delivery functions together, and to centralise responsibility for digital transformation.

What will it now do?

- 7.8 This instrument transfers the functions of NHS Digital to NHS England and abolishes NHS Digital. Broadly speaking, the transfer of functions is made by substituting references to “NHS England” for references to the Health and Social Care Information centre or “NHS Digital” in the relevant provisions, or simply omitting the references to NHS Digital (where NHS England is already referred to).
- 7.9 In all instances in which the instrument substitutes or inserts a reference to NHS England, it is referred to by that name rather than its previous name of “the National Health Service Commissioning Board”. The Board was renamed “NHS England” by section 1 of the Health and Care Act 2022 (the 2022 Act). Certain items of secondary legislation amended in this way still contain references to NHS England by its old name of the NHS Commissioning Board or simply “the Board”. However, under paragraph 1(3) of Schedule 1 to the 2022 Act, such references to the NHS Commissioning Board will fall to be read, in relation to any time on or after 1 July 2022, as references to NHS England. It is also intended that there will be another instrument implementing amendments consequential on the 2022 Act which will update the remaining references to “the Board” to “NHS England”.
- 7.10 In certain items of secondary legislation there are references to NHS Digital as a “health service body”. Such legislation establishes certain bodies and includes eligibility rules for members. In overview, these rules provide that a person who has been removed or otherwise dismissed from certain positions in “health service bodies” is ineligible to become a member of the body the legislation establishes. In such legislation, the reference to NHS Digital in the definition of “health service body” has been retained to ensure that those disqualification provisions continue to apply to persons removed from relevant roles in NHS Digital. The exception to this approach is where the relevant legislation already includes a definition of “former health service body”; in such legislation, we have added NHS Digital to this definition and removed it from the definition of “health service body”. This is consistent with the approach that has been adopted in relation to the abolition of other bodies such as Monitor and Clinical Commissioning Groups.
- 7.11 The instrument repeals various powers of direction under the 2012 Act which relate to how NHS Digital must exercise its functions. This is to avoid duplication with section

⁴ <https://www.gov.uk/government/publications/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs/putting-data-digital-and-tech-at-the-heart-of-transforming-the-nhs>

13ZC of the National Health Service Act 2006 which can be used for this purpose in relation to NHS England. The instrument also revokes regulations relating to NHS Digital's role in maintaining a database of quality indicators (the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013), the existing iteration of which will transfer to NHS England under the general transitional provision.

7.12 Additionally, the instrument introduces certain new requirements on NHS England which are intended to strengthen the protection of confidential information by NHS England when exercising the data functions transferred to it by this instrument. These new requirements comprise a requirement for NHS England to report on how effectively it discharged its relevant data functions (via an amendment to section 13U of the National Health Service Act 2006) and a new duty for the Secretary of State to issue guidance to NHS England about the exercise of its "relevant data functions" and connected functions (new section 274A of the 2012 Act).

7.13 The guidance is to be prepared by the Secretary of State after consulting NHS England and other persons that the Secretary of State considers appropriate, and NHS England will have a duty to have regard to the guidance. It is intended that such guidance may include guidance in connection with matters such as:

- (a) independent expert advice on, and scrutiny of, the exercise of NHS England data functions, in relation to:
 - (i) codes of practice prepared under section 263(1) of the 2012 Act;
 - (ii) requests for the dissemination of confidential information;
 - (iii) other processes, policies and procedures in respect of the collection and dissemination of such information;
 - (iv) contractual terms and other safeguards concerning the protection of confidential information in agreements with third parties;
- (b) the manner in which, and the time within which, such advice or scrutiny may be sought;
- (c) from whom such advice or scrutiny may be sought;
- (d) the purposes for which independent scrutiny is to be established.

7.14 Regulation 6 of the instrument includes transitional provisions to ensure that NHS England must (or, where appropriate, may) continue to fulfil any functions of NHS Digital which are in progress (or not yet started) at the time of the transfer. These provisions ensure, for example, that any outstanding directions from the Secretary of State under section 254 of the 2012 Act, requests under section 255 of the 2012 Act and directions under regulation 32 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 must be considered or complied with by NHS England. Outstanding directions from NHS England to NHS Digital are addressed separately in regulation 3, as the power under which they were made has been repealed (in relation to NHS England).

7.15 Regulation 2(2) of the instrument abolishes NHS Digital.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union or trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 In developing this instrument, consent was requested from, and provided by, the Devolved Administrations. NHS England and NHS Digital, the Information Commissioner's Office and the National Data Guardian were also consulted, and their comments were considered and incorporated where appropriate.

11. Guidance

11.1 The new section 274A of the Health and Social Care Act 2012, inserted by this instrument, will require the Secretary of State to produce guidance for NHS England about the exercise of the "relevant data functions" or any of its other functions in connection with the relevant data functions. NHS England must have regard to the guidance when exercising its data functions. This is set out in more detail at paragraph 7.13.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because this instrument simply transfers existing functions and we expect little to no impact on businesses, charities, voluntary bodies or the public sector.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is through ongoing accountability arrangements for NHS England and reporting to Ministers and Parliament. NHS England will produce an annual report on how it has exercised the functions which are transferring to it.

14.2 The changes set out in this instrument aim to bring together the national leadership of data and digital policy and delivery, in a single organisation. The outcome will be subject to internal review after 12 months.

15. Contact

15.1 Gareth James at the Department of Health and Social Care, Telephone: 0113 2545328 or email: gareth.james@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Louise Greenrod, Deputy Director for Data Policy, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Markham, Parliamentary Under-Secretary at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.