EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE INFORMATION STANDARDS (PROCEDURE) REGULATIONS 2025

2025 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. Declaration

2.1 Minister Karin Smyth, Minister of State for Health (Secondary Care) at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Louise Greenrod, SCS1 for Data Policy, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Andrew Moody at the Department of Health and Social Care email: Andrew.moody@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 These regulations make provision about the new procedure that must be followed by the Secretary of State for Health and Social Care and/or NHS England (one or both will be "the responsible authority") when preparing and publishing information standards, under section 250 of the Health and Social Care Act 2012 (HSCA 2012), as amended by the Health and Care Act 2022 (HCA 2022).

4.2 Information standards relate to the processing of health and adult social care information. They define a common set of requirements that must be followed when health and adult social care providers use, process and share information described in an information standard published under these provisions.

4.3 When preparing or publishing an information standard, the responsible authority must follow the procedures set out in these regulations. This includes seeking advice from and/or involving such persons as the responsible authority considers to have relevant expertise, ensuring the required information is included in an information standard when published, and reviewing an information standard at such intervals as considered appropriate.

Where does the legislation extend to, and apply?

4.4 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.5 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England only.

5. Policy Context

What is being done and why?

5.1 Currently, the health and adult social care system lacks a joined up approach to technology and data solutions. This is in part due to low compliance with information standards, with only 42% of sampled health and adult social care providers, and 56% of IT suppliers to the health and adult social care system, being in compliance with core information standards. Low compliance with information standards makes it hard to achieve change or deliver improvements that are consistent across health and adult social care. ('Core information standards' are those identified as being fundamental for the effective operation of a health and care system, characterised by the seamless exchange of information across health and social care settings.)

5.2 To improve compliance, changes made by the HCA 2022 make information standards mandatory and allow them to be applied to private providers of health and adult social care who are registered with the Care Quality Commission (CQC).

5.3 To support these improvements to the information standards framework, this instrument imposes a specific process that will be followed in developing and publishing all information standards. This instrument sets out the process that must be followed. This includes requirements for seeking the views and/or advice from those with relevant expertise (this may include clinical staff, data architects, IT suppliers, and/or Information Governance specialists) during the development of an information standard, which will ensure future information standards are able to meet the needs of the system.

5.4 The procedure outlined in this instrument will mean that information standards are fit-for-purpose, kept up-to-date and reviewed regularly as needed, and that the standards keep pace with technical developments and evolving priorities.

5.5 Making regulations on procedures for preparing and publishing information standards is an integral part of a wider set of measures which are intended to improve the entire information standards framework, including in terms of content, application and compliance. They are also being brought into force at the same time as the other amendments to sections 250 and 251 made by section 95 of the HCA 2022 are being commenced (including those referred to above).

What was the previous policy, how is this different?

5.6 Legal powers to publish information standards for public health and adult social care providers were set out in section 250 of the HSCA 2012. Under that Act, there was no regulatory requirement that set out the procedure to be followed when preparing and publishing an information standard. As such, existing standards have not undergone a standardised approach to their preparation or review. This inconsistency has contributed to low compliance with information standards, by making it harder for health and adult social care providers to understand what they are being asked to do.

5.7 The requirement to set out a statutory procedure in regulations was provided in the amendments made to section 251 of the HSCA 2012 by section 95 of the HCA 2022,

which is being commenced at the same time as these regulations. Information standards will only become mandatory once they have been through the new procedure as set out in this instrument.

5.8 This instrument will introduce requirements for seeking advice from those with relevant expertise (regulation 3) and involving persons considered appropriate (regulation 4). These requirements will better ensure that information standards are developed that are, in practice, deliverable.

5.9 Regulation 4 might include those referred to in regulation 3 but will also cover those potentially affected by a standard or who might be advantaged/disadvantaged by it (patients, medical professionals etc). For regulation 3, that advice would inform technical aspects of the information standard itself, whereas regulation 4 is expected to be broader, cover those potentially affected by the standard or those who may be able to give a more system-wide / strategic view of how it would fit in with everything else. Further, for regulation 4, 'involvement' would not necessarily mean asking for information but could just be about providing it.

5.10 A regulation-based approach will facilitate uniformity in how views and/or advice is taken into consideration when developing information standards. It will also facilitate a more strategic approach to how information standards are used, by ensuring wider considerations are taken into account – such as capacity of the system to implement standards, supporting priority use cases and accounting for international practices.

5.11 In order to ensure a frictionless transition from the existing information standards system to the new process for introducing mandatory information standards, information standards made under the existing system, which are not mandatory, will continue to have effect until they have been revoked, have expired, or gone through the procedures in these regulations to become mandatory and apply to a wider range of health and adult social care providers. Preserving existing standards will ensure there is continuity and prevent disruption to service delivery.

6. Legislative and Legal Context

How has the law changed?

6.1 Changes to be made by section 95 of the HCA 2022 amend section 250 of the HSCA 2012 to extend the potential application of information standards to additionally capture CQC-regulated private health and adult social care providers.

6.2 The HCA 2022 also requires persons to whom information standards apply to comply with the standard, in place of the existing duty to have regard to information standards – i.e. making the standards mandatory. However, the Secretary of State will continue only to be obliged to have regard to standards published by NHS England which apply to the Secretary of State.

6.3 Additionally, the HCA 2022 introduced a duty requiring a statutory procedure to be introduced by regulations which must be followed during the preparation and publication of the new mandatory information standards. Section 95 of the HCA 2022 also allows that regulations may set out a requirement for an information standard to be reviewed.

6.4 This instrument sets out this new procedure that must be followed for preparation, publication and review of information standards. These regulations mean that when preparing or publishing an information standard, the Secretary of State and/or NHSE will be required to:

- Seek advice from such persons considered to have relevant expertise
- Involve such persons as considered appropriate
- Have regard to any advice received or views obtained
- Include matters specified in regulation 6 in an information standard when published
- Maintain a list of information standards
- Review an information standard at such intervals as considered appropriate

6.5 It is being brought into force at the same time as commencement of the amendments made by section 95 HCA 2022. The commencement regulations contain savings and transitional provisions to allow for the information standards that were prepared and published under the previous non-statutory procedure and which are in effect at the commencement date to remain subject to that previous procedure until they are revoked, expire or replaced by a similar, mandatory information standard.

6.6 Accordingly, the HSCA 2012 continues to have effect for the purposes of such an information standard as if it had not been amended by section 95 of the HCA 2022. In practice, this means the continued application of section 250(6) of the HSCA 2012 to existing information standards, thereby maintaining the requirement to have regard to those information standards.

Why was this approach taken to change the law?

6.7 Enacting secondary legislation under HCA 2022 will require all health and social care providers to implement the required information standards at the same pace (moving public providers from the needing to have 'regard' to information standards to a requirement to comply with them, and making private providers comply with standards for the first time) giving clarity on the priority and sequencing of implementation and avoiding confusion amongst providers.

6.8 There was no prior regulatory requirement to set out the procedure to be followed when preparing and publishing an information standard. As such, existing standards have not undergone a standardised approach to their preparation or review. This inconsistency has contributed to low compliance with information standards, by making it harder for health and adult social care providers to understand what they are being asked to do. Therefore, these provisions would ensure that mandatory standards are drafted in accordance with specific procedures, including consulting with people with relevant expertise (such as clinical staff, data architects, IT suppliers, and/or Information Governance specialists).

7. Consultation

Summary of consultation outcome and methodology

7.1 Public consultation was undertaken in spring 2024, to seek views on proposals for the procedure to be set out in regulations in connection with preparing and publishing information standards for health and adult social care in England.

7.2 The consultation was launched on 15 February 2024 and ran for 6 weeks, until 28 March 2024. There were 132 responses to the consultation. Of these, 56 (42.4%) responded on behalf of an organisation, 55 (41.7%) as an individual sharing their professional views, and 21 (15.9%) as an individual sharing their personal views.

7.3 In general, responses received were in support of the proposals, with a few suggestions for adjustments and refinements that have been taken into consideration during the drafting of these procedures.

7.4 Full detail of the department's response to the consultation was published on 22nd November 2024 and can be found at Information standards for health and adult social care in England: consultation response - GOV.UK[1].

8. Applicable Guidance

8.1 Guidance is not required

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment for the Health and Care Act 2022 section 95 on Information Standards is submitted with this memorandum and published on the Legislation.gov.uk website.

9.2 A full impact assessment has not been prepared for this instrument specifically because the instrument will not have an impact to business over £5 million.

Impact on businesses, charities and voluntary bodies

9.3 The procedures set out in this instrument will be the responsibility of the Secretary of State and/or NHS England, and outline procedures which the Secretary of State and/or NHS England must follow when preparing and publishing an information standard.

9.4 When s95 HCA 2022 is commenced, the main impact on business is related to the introduction of mandatory information standards themselves, rather than the procedures set out in this instrument.

9.5 To ensure they meet the mandatory information standards, private hospitals, private adult social care providers and private GPs will need to upgrade clinical IT systems, train staff and adapt their workflows to ensure seamless data sharing.

9.6 Compliance costs for Small and Micro Businesses represent a higher proportion of their total capacity and resources than larger businesses. Achieving system wide interoperability will require all the constituent parts of the health and care system to adopt common data standards. Exemption of any size business would undermine the policy objective and so has not been considered for small and micro businesses.

9.7 It is estimated that enacting secondary legislation under the amendments made by section 95 of the HCA 2022 could generate benefits of £217.7 million in a ten-year period in present value terms.

[1] https://www.gov.uk/government/consultations/information-standards-for-health-and-adult-social-care/outcome/information-standards-for-health-and-adult-social-care-in-england-consultation-response

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation is that the Secretary of State must carry out a review of the regulatory provision in the instrument within 5 years of when the instrument comes into force, and subsequently at 5-year intervals.

10.2 As this instrument is not made under the relevant European Union Acts (as defined at 13.1), no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This SI is the first set of regulations made under the amended section 251 HSCA 2012. It makes provision about the procedure to be followed in connection with the preparation and publication of information standards under section 250 HSCA 2012. It introduces new procedural duties for the preparation and publication of such standards going forward.

12. European Convention on Human Rights

12.1 The Minister of State for Health (Secondary Care) has made the following statement regarding Human Rights:

"In my view the provisions of the Health and Social Care Information Standards (Procedure) Regulations 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").