Draft Regulations laid before Parliament under section 304(5)(ja) of the Health and Social Care Act 2012 (c. 7), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2025 No.

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

The Health and Social Care Information Standards (Procedure) Regulations 2025

Made - - - - ***

Coming into force in accordance with regulation 1(1)

The Secretary of State for Health and Social Care makes these Regulations in exercise of the powers conferred by sections 251(1) and 304(9) and (10) of the Health and Social Care Act 2012(**a**).

In accordance with section 251(2) of that Act, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

In accordance with section 304(5)(ja)(**b**) of that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement, interpretation and extent

1.—(1) These Regulations may be cited as the Health and Social Care Information Standards (Procedure) Regulations 2025 and come into force 28 days after the day on which they are made.

(2) In these Regulations, "the responsible authority" means the Secretary of State, NHS England or both acting jointly (as the case may be).

(3) These Regulations extend to England and Wales.

(**a**) 2012 c. 7. Section 251 was substituted by section 95(3) of the Health and Care Act 2022 (c. 31). Section 95 comes into force on the same day as these Regulations.

(**b**) Section 304(5)(ja) was inserted by section 95(5) of the Health and Care Act 2022 and comes into force on the same day as these Regulations.

Procedures in connection with information standards

2.—(1) Subject to paragraph (2), when preparing or publishing an information standard under section 250 of the Health and Social Care Act 2012 (powers to publish information standards) (**a**), the responsible authority must follow the requirements set out in regulations 3 to 9.

(2) Regulations 3 to 5 do not apply to the preparation of an information standard that is intended to replace a previously published information standard—

(a) where the responsible authority is satisfied that the replacement of that information standard will not have a significant effect on those to whom it applies; or

(b) to the extent that the new information standard is required in order to discharge a legal obligation.

Seeking advice

3. Where the responsible authority considers that there is a person with expertise relevant to the subject matter or content of an information standard, the responsible authority must seek advice from that person during the preparation of that information standard.

Involvement of persons

4.—(1) Where the responsible authority considers that it is appropriate to involve a person, having regard to the subject matter or content of an information standard, the responsible authority must involve that person in the preparation of that standard.

(2) For the purposes of paragraph (1), involving a person may include consulting a person or providing a person with information on the effect of that standard.

Having regard to matters

5. The responsible authority must have regard to the following matters during the preparation of an information standard—

(a) any advice received under regulation 3;

(b) any views obtained under regulation 4;

(c) such other matters as the responsible authority considers appropriate.

Matters to include in published information standards

6. The responsible authority must include the following in an information standard—

(a) the title of the information standard;

(b) the identity of the responsible authority and their contact details;

(c) the date that the information standard takes effect;

(d) the date of publication of the information standard;

(e) a statement that the information standard must be complied with or had regard to (as the case may be);

(f) the consequences, if any, of failure to comply with the information standard(**b**);

(**a**) Relevant amendments are made by section 95, paragraphs 1(1) and 19 of Schedule 1 and paragraph 22 of Schedule 9 of the Health and Care Act 2022 and paragraph 172 of Schedule 19(1) of the Data Protection Act 2018 c. 12.

(**b**) For enforcement of information standards against persons other than public bodies, *see* section 277E of the Health and Social Care Act 2012. Section 277E was inserted by section 100 of the Health and Care Act 2022.

(g) a statement that the Secretary of State may require a person to provide the Secretary of State with documents, records or other information for the purposes of monitoring the person's compliance with the information standard ("monitoring purposes")(**a**);

(h) the consequences of failure to comply with a requirement to provide information for monitoring purposes or the provision of information in response to such a requirement that is false or misleading to a material extent(**b**);

(i) information about any guidance issued by the responsible authority about implementation of the information standard;

(j) any significant revisions made to the information standard since it was last published;

(k) such other information as the responsible authority considers appropriate.

List of information standards

7.—(1) The responsible authority must—

(a) maintain a list of information standards that it has prepared and published; and

(b) where the responsible authority is the Secretary of State, provide that list to NHS England when requested by NHS England to do so.

(2) NHS England must—

(a) publish a list of the information standards prepared and published by each responsible authority; and

(b) ensure that list is kept up to date.

Review of information standards

8. The responsible authority must review an information standard at such intervals as the responsible authority considers appropriate.

Revocation of an information standard

9.—(1) Subject to paragraph (2), regulations 3 to 5 apply to the revocation of an information standard as they apply to the preparation of a standard.

(2) Regulations 3 to 5 do not apply to revocation of an information standard, to the extent that revocation of that standard is required in order to discharge a legal obligation.

Signed by authority of the Secretary of State for Health and Social Care.

Name
..of State
Date Department of Health and Social Care

(**a**) *See* section 251ZA of the Health and Social Care Act 2012 as to the Secretary of State's power to require a person to provide the Secretary of State with documents, records or other information for the purposes of monitoring the person's compliance with the information standards. Section 251ZA was inserted by section 95 of the Health and Care Act 2022. Section 251ZA comes into force at the same time as these Regulations.

(**b**) For enforcement of the requirement to provide information for monitoring purposes against persons other than public bodies, or for providing information that is false or misleading to a material extent, *see* section 277E of the Health and Social Care 2012.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision about the procedure to be followed in connection with the preparation and publication of an information standard under section 250 of the Health and Social Care Act 2012 (c. 7) ("the 2012 Act").

An information standard is a standard in relation to the processing of information and may be prepared by the Secretary of State, NHS England or both ("the responsible authority").

An information standard may apply to the Secretary of State, NHS England, a public body which exercises functions in connection with the provision of health care or of adult social care in England or any person, other than a public body, who is required to be registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 in respect of the carrying out of a regulated activity (within the meaning of Part 1 of that Act).

These Regulations set out what must be included in information standards and the procedures that must be followed when preparing and publishing them. They also set out that the duties to seek advice, involve persons and have regard to certain matters also apply to information standards intended to replace a previously published information standard, other than when the responsible authority is satisfied that replacement of that information standard will not have a significant effect on those to whom it applies, or to the extent that it is required to be published in discharge of a legal obligation.

The Regulations also make provision for the review and revocation of information standards, as well as requiring each responsible authority to maintain a list of information standards and for NHS England to publish each list.

A full impact assessment has been prepared in relation to section 95 of the 2022 Act, and a copy is available at www.legislation.gov.uk. A hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

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