Department of Health & Social Care

Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

Amanda Pritchard
Chief Executive
NHS England

14 March 2024

Dear Amanda,

1. Outcomes and Registries Directions 2024

1.1 I am writing on behalf of the Secretary of State for Health and Social Care (**the Secretary of State**) to give Directions to **NHS England**.

1.2 These Directions are given in exercise of the powers conferred by sections 254(1), 260(2)(d), 261(2)(e) and 304(9) to (12) of the Health and Social Care Act 2012[1] (**the 2012 Act**) and sections 13ZC and 272(7) and (8) of the National Health Service Act 2006[2] (**the 2006 Act**).

1.3 These Directions are to be known as the **Outcomes and Registries Directions 2024** and come into force on the date after the day on which they are signed.

2. Requirement for these Directions

2.1 In accordance with section 254(2)(b) of the 2012 Act, the Secretary of State considers that it is in the interests of the health service in England or of the

[1] 2012 c.7 (the 2012 Act). Relevant amendments were made by the Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98).
[2] 2006 c.41. Section 13ZC was inserted by section 45 of the Health and Care Act 2022 (c.31).

recipients or providers of adult social care in England for these Directions to be given.

2.2 In accordance with section 254(5) of the 2012 Act, the Secretary of State has consulted NHS England before giving these Directions.

2.3 In accordance with section 13ZC(5) of the 2006 Act, the Secretary of State considers these Directions to be in the public interest.

3. Priorities, Policies and Non-Statutory Guidance

In exercising functions under these Directions, NHS England must have regard to such priorities, policies and non-statutory guidance[3] of the Secretary of State as the Secretary of State may notify in writing from time to time to NHS England.

4. Purpose

4.1 The purpose of these Directions (**the Purpose**) is to require NHS England to establish and operate an information system to collect and analyse information from relevant health and social care bodies[4] and other organisations, including private healthcare providers, in England for the purposes of improving clinical safety and patient outcomes, reducing variation in clinical practice and to support the NHS and government response to the recommendations of the Independent Medicines and Medical Devices Safety Review[5] and the Paterson Inquiry report[6].

4.2 The Purpose includes but is not limited to:

4.2.1 Identifying and understanding information relating to patient and event level, clinical procedures and outcomes across medical conditions, for improved safety, vigilance and clinical effectiveness. The outcome registries information system and outcomes registries platform will enable:

(a) improved clinical data collection submission, quality assurance and validation near to the episode of care, addressing key data limitations of current NHS data sets, including:

(i) accurate consultant and procedure code attribution;

[3] In addition, NHS England has a duty to have regard to statutory guidance issued by the Secretary of State under section 274A of the 2012 Act: NHS England's protection of patient data, 23 May 2023, as the same may be updated from time to time.
[4] See section 259 of the 2012 Act as to the meaning of "health and social care body".
[5] The report is available at: https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-update-report-on-government-implementation/independent-medicines-and-medical-devices-safety-review-update-report-on-government-implementation
[6] The report is available at: https://www.gov.uk/government/publications/paterson-inquiry-report

(ii) biomedical technology (e.g. medical device / medicine) attribution;
(iii) clinical observations and patient reported outcome data collection; and
(iv) clinician data validation close to the episode of care;

(b) improved patient-reported outcome, experience and consent data collection(s), with structured and unstructured patient feedback about the quality of their care;

(c) implementation of a national, mandatory Medical Device Outcome Registry that includes:

(i) monitoring of patient outcomes achieved by hospital, surgeon clinician, biomedical technology, manufacturer and individual product;
(ii) identifying and understanding patient information relating to medical devices. This will include reference data about manufacturers of medical devices, e.g. batch number, serial number;
(iii) collecting and evaluating product data and evidence from manufacturers related to their products;
(iv) identifying and understanding information about patients relating to clinical procedures to facilitate patient, clinician and provider communications, for patent safety and assurance purposes, such as device-patient recall; and
(v) analysis and evaluation of pre-market and clinical trial biomedical technology usage, performance and outcomes;

(d) development and delivery of comparative analysis measures and national, sub-national, provider and clinician / patient level reporting, including:

(i) analysis and evaluation to support informed clinical and patient decision making in direct care, and in selection of the appropriate treatment options;
(ii) provision of whole consultant practice analysis, performance appraisal or patient safety and outcomes analysis and improved outlier analysis and clinical feedback for direct care and clinical performance appraisal; and
(iii) delivery of comparative measures and analysis with which to detect emerging quality and safety signals, monitoring of where clinical and patient reported outcomes fall below

expected thresholds and to support investigation of problems and appropriate action when required;

(e) improved access to outcomes and registries data for: patients about their care, clinicians about their performance and practice, NHS England about comparative performance and value, biotechnology manufacturers about the safety and effectiveness of their products and organisations researching areas such as quality improvement, clinical effectiveness, innovation and value; and

(f) identifying and understanding information to support the planning and commissioning of health services.

4.2.2 The Purpose includes setting up new registries and consolidating a range of existing outcome registries, patient reported outcome datasets and audits over time, into a shared delivery model. The Outcomes and Registries datasets within scope of these Directions are published on Outcomes and Registries List[7] and will be updated regularly in line with the Requirements Specifications (as defined below).

5. Establishing and operating information systems

5.1 It is anticipated that there will be multiple collections within the scope of these Directions. Each collection will have a requirements specification published alongside these Directions as may be updated periodically by the Secretary of State in consultation with NHS England (**the Requirements Specifications**).

5.2 The Secretary of State directs NHS England to establish and operate a system for the collection and analysis of the information described in and in accordance with the related Requirements Specifications.

5.3 The Requirements Specifications published at the date of these directions are:

5.3.1 The Medical Device Outcome Registry Requirements Specification version 1.0 published with these Directions; and

5.3.2 The National Major Trauma Registry Requirements Specification version 1.0 published with these Directions,

as updated periodically by the Secretary of State in consultation with NHS England.

5.4 The Secretary of State directs NHS England to analyse the information which NHS England obtains by complying with these Directions (**the**

[7] https://www.england.nhs.uk/outcomes-and-registries-programme/

Information), as may be required by the Secretary of State or as NHS England considers necessary to achieve the Purpose. Such analysis includes:

5.4.1 analysis by reference or linkage to information described in the Requirements Specifications;

5.4.2 analysis for data quality purposes, including undertaking comparison and consistency analysis of the same or similar information obtained by complying with other directions under section 254 of the 2012 Act or requests under section 255 of the 2012 Act.

5.5 The Secretary of State directs NHS England to take such steps as NHS England considers appropriate to maintain data quality, accuracy and consistency in relation to the Information.

5.6 In exercising functions under these Directions, NHS England must act in accordance with the Requirements Specifications and generally in such a way as to achieve the Purpose.

6. Service Levels etc

In exercising functions under these Directions, NHS England must act in accordance with the service levels, support and monitoring requirements, and the reporting and governance requirements notified by the Secretary of State in writing to NHS England as at the date these Directions come into force, or as those requirements are amended and notified by an authorised officer of the Department for Health and Social Care on behalf of the Secretary of State in writing to NHS England from time to time.

7. Publication

For the purposes of section 260(2)(d) of the 2012 Act, any of the Information that is specified in any Requirements Specification as not for publication (**Non-Published Data**) is specified as information that under section 260(1) and section 260(2)(d) of the 2012 Act, must not be published[8].

8. Dissemination

Despite the prohibition on publication set out in paragraph 7, NHS England may disseminate the Non-Published Data under section 261(1) of the 2012 Act[9].

9. Fees and Accounts

NHS England must keep proper accounts, and proper records in relation to the accounts, in connection with these Directions.

[8] Such information is specified as information falling within section 260(2)(d) and the prohibition in section 260(1) on publishing information accordingly applies to it.
[9] See section 261(2)(e) of the 2012 Act for NHS England's power to disseminate information which it is prohibited from publishing only by virtue of a direction given under section 260(2)(d).

10. **Duration**

NHS England must exercise functions under these Directions until they are revoked by a further direction in writing by an authorised officer of the Department of Health and Social Care on behalf of the Secretary of State.

11. **Review of these Directions**

These Directions will be reviewed from time to time. Any amendments to the Directions or the Requirements Specifications will only be made after consultation with NHS England.

12. **Revocation**

The Surgical Devices and Implants Directions 2020[10] are revoked.

Yours sincerely

Louise Greenrod

Signed by authority of the Secretary of State

Date signed: 14 March 2024

[10] Surgical devices and implants Directions. The Directions were given by the Secretary of State to the Health and Social Care Information Centre (NHS Digital) on 13 July 2020. NHS Digital was abolished, and its functions transferred to NHS England, with effect from 1 February 2023, by the Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98). By virtue of regulation 6, those Directions have effect as if references to NHS Digital were references to NHS England (and the Directions accordingly have effect as if given to NHS England).