

EXPLANATORY MEMORANDUM TO
THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
(CONSTITUTION AND FUNCTIONS) AND THE HEALTH AND SOCIAL
CARE INFORMATION CENTRE (FUNCTIONS) REGULATIONS 2013

2013 No. 259

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
 - 2.1 These Regulations confer a number of functions on the National Institute for Health and Care Excellence (NICE) and the Health and Social Care Information Centre (the Information Centre) which are to be established as executive non-departmental public bodies under the Health and Social Care Act 2012. The Regulations will enable NICE and the Information Centre to carry out similar functions to those that the predecessor bodies currently perform as Special Health Authorities.
3. **Matters of special interest to the Joint Committee on Statutory Instruments or the Select Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 Part 8 and Chapter 2 of Part 9, (together with Schedules 16, 17, 18 and 19) of the Health and Social Care Act 2012 provide for the dissolution of two Special Health Authorities: the National Institute for Health and Clinical Excellence (the Institute) and the Health and Social Care Information Centre (HSCIC) and for the establishment of two new bodies as executive non-departmental public bodies to take on similar functions but with remits extended to include, in the case of NICE, social care and in the case of the Information Centre, adult social care. These Regulations represent the first uses of powers within Part 8 and Chapter 2 of Part 9 enabling certain functions to be conferred on each of the new bodies.
 - 4.2 Regulation 7 makes provision that requires the NHS Commissioning Board, clinical commissioning groups and, with respect to their public health functions, local authorities to comply with a NICE technology appraisal recommendation following a direction of the Secretary of State. The regulation will underpin the NHS Constitution right to “drugs and treatments that have been recommended by NICE technology appraisal guidance for use in the NHS, if your doctor says

they are clinically appropriate for you.” A requirement to fund treatments recommended by NICE technology appraisal guidance previously applied to primary care trusts. This provision reflects the Government commitment to replicate the effect of the funding direction in the new NHS structures.

Secretary of State’s duty to promote autonomy

- 4.3 The Health and Social Care Act 2012 confers on the Secretary of State a number of duties to which the Secretary of State must have regard when exercising functions, including the duty to promote the autonomy of others exercising functions in relation to the health service. The Regulations are consistent with this duty. Currently, the Institute and HSCIC, as Special Health Authorities, exercise functions under Secretary of State direction and therefore the nature of their core functions and powers can be modified at the discretion of Ministers. From 1 April 2013, the bodies will have their functions set out in primary legislation and in or under Regulations, which can be changed only subject to the will of Parliament. This will safeguard these two important bodies for the future.

5. Territorial Extent and Application

- 5.1 This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- 7.1 The predecessor bodies to NICE and the Information Centre were established as Special Health Authorities in 1999 and 2005, respectively. The Government White Paper, *Equity and Excellence: Liberating the NHS*¹, stated that each organisation would be put on a firmer statutory footing in primary legislation. The main policy objective was to safeguard and strengthen the position of these two key bodies by making provision for their functions in legislation. The new bodies will have similar but more transparent functions to those of the predecessor bodies, which for NICE now extend to social care and for the Information Centre, adult social care. The Regulations ensure that the new bodies are able to carry out functions similar to those currently exercised by the Special Health Authorities more transparently. Part 3 of the Regulations will also enable the Information Centre to be directed by Secretary of State or the NHS Commissioning Board to exercise their respective functions for supporting the delivery of health and care IT systems.

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http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117794.pdf

8. Consultation outcome

- 8.1 The proposals to dissolve the current Special Health Authorities and establish them as executive non-departmental public bodies was consulted on as part of the proposals in the White Paper, *Liberating the NHS*. Respondents welcomed the proposed wider remit that NICE will have compared to its predecessor and the clearer role and powers for the Information Centre to collect and use information from across health and social care, compared to the predecessor body.
- 8.2 We have informally engaged with the Information Centre, NICE, the devolved administrations and other government departments on this Instrument. The bodies mentioned were content with the Regulations.

9. Guidance

- 9.1 We do not plan to issue guidance.

10. Impact

- 10.1 The regulations do not impact on small business or civil society organisations, therefore, no specific impact assessment has been completed for these Regulations.
- 10.2 Annex E of the combined Health and Social Care Bill Impact Assessment contains a section in relation to the proposed re-establishment of the Institute (pages 126 to 127), and therefore contains relevant information. Pages 136 to 137 of Annex E contain relevant information in relation to the HSCIC.
- 10.3 The combined Health and Social Care Bill Impact Assessment and coordinating document, and combined Equality analyses, can be found at the following link:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_123583

11. Regulating small business

- 11.1 The legislation does not apply to small business.

12. Monitoring & review

- 12.1 This instrument will not be specifically monitored.

13. Contact

For queries relating to Part 2 of this Instrument, please contact Jane Newton at the Department of Health, tel: 0113 254 5605 or e-mail: jane.newton@dh.gsi.gov.uk. For queries relating to Part 3 of this Instrument,

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