

2013 No. 259

NATIONAL HEALTH SERVICE, ENGLAND

**The National Institute for Health and Care Excellence
(Constitution and Functions) and the Health and Social Care
Information Centre (Functions) Regulations 2013**

<i>Made</i>	- - - -	<i>11th February 2013</i>
<i>Laid before Parliament</i>		<i>13th February 2013</i>
<i>Coming into force</i>	- -	<i>1st April 2013</i>

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 235(1) to (3), 237(1) to (3), (5)(b) and (c), and (7) to (9)(a), 238, 239(1), (4) and (5), 240(1) to (3), 242, 268(1) and (2), 269(1), 274(1)(d) and (6) to (8), and 304(1), (9) and (10) of, and paragraph 8(2) of Schedule 16 to, the Health and Social Care Act 2012(b):

PART 1

General

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

(2) These Regulations come into force on 1st April 2013.

(3) In these Regulations—

“the Act” means the Health and Social Care Act 2012;

“the 2006 Act” means the National Health Service Act 2006(c);

“the Board” means the National Health Service Commissioning Board(d);

“relevant date” means 1st April 2013.

(a) See section 237(11) of the Health and Social Care Act 2012 (“the Act”) for the definition of “specified” in relation to the exercise of the powers in section 237 to make regulations.
(b) 2012 c. 7.
(c) 2006 c. 41.
(d) The National Health Service Commissioning Board (“the Board”) is established by section 1H of the National Health Service Act 2006 (“the 2006 Act”). Section 1H is inserted by section 9 of the Act.

PART 2

The National Institute for Health and Care Excellence

Interpretation of this Part

2. In this Part—

“carer” means an adult who provides or intends to provide care for another person;

“CCG” means a clinical commissioning group(a);

“Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(b);

“health technology” may include—

(a) a medicinal product to which Directive 2001/83/EC applies(c);

(b) a medical device;

(c) a diagnostic technique;

(d) a surgical procedure or other therapeutic technique;

(e) a therapeutic technology other than a medicinal product to which Directive 2001/83/EC applies, medical device, diagnostic technique or surgical procedure;

(f) a system of care; or

(g) a screening tool;

“highly specialised health technology” means a health technology intended for use in the provision of services for rare and very rare conditions provided for in regulations under section 3B(1)(d) of the 2006 Act(d);

“highly specialised technology recommendation” means a recommendation made by NICE following an appraisal of the benefits and costs of a highly specialised health technology conducted by NICE in accordance with NICE’s published methods and processes for appraisal of highly specialised health technologies that results in a positive assessment;

“the Institute” means the Special Health Authority known as the National Institute for Health and Clinical Excellence(e);

“life sciences industry” includes the pharmaceutical, medical technology and medical biotechnology industries;

“NICE” means the National Institute for Health and Care Excellence established under section 232 of the Act;

“patient” means any person who is receiving treatment as part of the health service(f) in England;

“technology appraisal recommendation” means a recommendation made by NICE following an appraisal of the benefits and costs of a health technology conducted by NICE in accordance with NICE’s published methods and processes for appraisal of health technologies that results

(a) A clinical commissioning group (“CCG”) is a body established under section 14D of the 2006 Act. Section 14D is inserted by section 25(1) of the Act. *See also* section 11 of the 2006 Act, inserted by section 10 of the Act.

(b) OJ No L 311, 28.11.2001, p.67. Directive 2001/83/EC was last amended by Directive 2012/26/EU (OJ No L 299, 27.10.2012, p. 1 to 4).

(c) *See* Articles 1(2), 2(1) and 3 of Directive 2001/83/EC.

(d) *See* regulations 7, 10 and 11 of, and Schedule 4 to, the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, S.I. 2012/2996.

(e) The National Institute for Health and Clinical Excellence was established by article 2 of the National Institute for Clinical Excellence (Establishment and Constitution) Order 1999, S.I. 1999/220, as amended by S.I. 1999/2219, 2002/1750, 2005/497 and 2012/476 and abolished by section 248 of the Act, which is to come into force on 1st April 2013 (*see* the Health and Social Care Act 2012 (Commencement No. 4, Transitional, Savings and Transitory Provisions) Order 2013, S.I. 2013/160 (C. 9)).

(f) “The health service” is defined in section 247 of the Act.

in a positive assessment (but does not include a highly specialised technology recommendation);

“treatment” means an intervention that is intended to manage a person’s disease, condition or injury and includes prevention, examination and diagnosis.

Procedures for conflicts of interests of members

3.—(1) NICE must publish procedures for dealing with conflicts of interests of members of NICE or members of a committee or sub-committee of NICE.

(2) The procedures must address conflicts or potential conflicts arising in connection with a pecuniary or other personal interest.

(3) The procedures may provide amongst other things for—

- (a) arrangements regarding the divestment, or declaration of, or disability in proceedings by reason of, a pecuniary or other personal interest; or
- (b) the settlement of disputes regarding a pecuniary or other personal interest.

Supply of quality standards to devolved authorities or other persons

4.—(1) NICE may supply a quality standard(a) to a devolved authority(b) or other person (whether or not in the United Kingdom), and for that purpose NICE has power to make such adjustments to the quality standard as NICE considers appropriate.

(2) Adjustments may, in particular, relate to—

- (a) the organisation of health or social care services in the territory—
 - (i) of the devolved authority, or
 - (ii) in which the person exercises functions, undertakes activity or is established; or
- (b) a language used in the territory of a devolved authority or by the person to whom a quality standard is supplied.

(3) NICE may impose a charge for or in connection with the supply of a quality standard to a devolved authority or other person.

(4) Subject to paragraph (5), a charge imposed pursuant to paragraph (3) may be calculated as NICE considers—

- (a) appropriate to enable NICE to recover the cost of making an adjustment to the quality standard or supplying the quality standard; or
- (b) to be the appropriate commercial basis.

(5) NICE may impose a charge on a devolved authority under paragraph (3) only if the charge is calculated so as to enable NICE to recover no more than the cost of making an adjustment to the quality standard or supplying the quality standard.

Advice, guidance, information and recommendations

5.—(1) NICE has the functions of giving advice or guidance, providing information or making recommendations about any matter concerning or connected with the provision of—

- (a) NHS services(c),
- (b) public health services(d), or
- (c) social care(e) in England.

(a) See section 234 for a description of a quality standard.
(b) “Devolved authority” is defined in section 235(4) of the Act.
(c) “NHS services” is defined in section 234(11) of the Act.
(d) “Public health services” is defined in section 234(11) of the Act.
(e) “Social care” is defined in section 233(3) of the Act.

- (2) In the case of a function conferred under paragraph (1)(a), the function—
- (a) is only exercisable on the direction of the Secretary of State or the Board;
 - (b) is subject to directions given by the Secretary of State or (as the case may be) the Board about NICE’s exercise of the function.
- (3) In the case of a function conferred under paragraph (1)(b) or (c), the function—
- (a) is only exercisable on the direction of the Secretary of State;
 - (b) is subject to directions given by the Secretary of State about NICE’s exercise of the function.
- (4) NICE must establish procedures for the giving of advice or guidance, the provision of information or the making of recommendations as NICE considers appropriate.
- (5) NICE must consult such persons as it considers appropriate in establishing a procedure under paragraph (4).
- (6) NICE must publish or disseminate any advice or guidance it gives or information it provides or a recommendation it makes—
- (a) to such health or social care bodies^(a) as NICE considers appropriate, and
 - (b) in such form and manner and at such time as NICE considers appropriate.
- (7) The Secretary of State must consult the Board before giving a direction under paragraph (2).
- (8) The Secretary of State must not give a direction under paragraph (2)(b) or (3)(b) about the substance of advice, guidance or recommendations of NICE.
- (9) The Board must not give a direction under paragraph (2)(b) about the substance of advice, guidance or recommendations of NICE.
- (10) NICE must keep under review and may revise as it considers appropriate any advice or guidance it gives, information it provides or recommendation it makes.
- (11) For the purposes of this regulation, a “recommendation” does not include a technology appraisal recommendation or a highly specialised technology appraisal recommendation.

Charges for NICE advice, guidance, information or recommendations

- 6.—(1) NICE may impose a charge for or in connection with the giving of advice or guidance, provision of information or making of a recommendation in exercise of the functions conferred by regulation 5(1) on persons other than—
- (a) the Secretary of State, or
 - (b) a person identified in a direction to NICE given by the Secretary of State under paragraph (2).
- (2) The Secretary of State may direct NICE in writing not to impose a charge in relation to—
- (a) advice, guidance, information or a recommendation specified in the direction, or
 - (b) advice, guidance, information or a recommendation of a description specified in the direction.
- (3) Subject to paragraph (4), a charge imposed pursuant to paragraph (1) may be calculated as NICE considers—
- (a) appropriate to enable NICE to recover the cost of providing the service; or
 - (b) to be the appropriate commercial basis.
- (4) NICE may impose a charge on a devolved authority under paragraph (1) only if the charge is calculated so as to enable NICE to recover no more than the cost of providing the service.

(a) “Health or social care body” is defined in section 237(11) of the Act.

NICE technology appraisal recommendations

7.—(1) NICE may make a technology appraisal recommendation—

- (a) in relation to a health technology identified in a direction given by the Secretary of State;
- (b) that recommends that relevant health bodies provide funding within a specified period to ensure that the health technology be made available for the purposes of treatment of patients.

(2) NICE must specify in a technology appraisal recommendation the period within which the recommendation in paragraph (1)(b) should be complied with.

(3) The period in paragraph (2) must be a period that begins on the date the recommendation is published by NICE and ends on the date 3 months from that date, unless paragraph (4) applies.

(4) In the circumstances described in paragraph (5), if NICE considers it appropriate, NICE must specify a longer period.

(5) The circumstances referred to in paragraphs (4) and (11) are—

- (a) the health technology cannot be appropriately administered until—
 - (i) training is,
 - (ii) certain health service infrastructure requirements including goods, materials or other facilities are, or
 - (iii) other appropriate health services resources, including staff, are, in place; or
- (b) the health technology is not yet available in England.

(6) A relevant health body must comply with a technology appraisal recommendation.

(7) A relevant health body for the purposes of this regulation is—

- (a) the Board in the case of a technology appraisal recommendation that applies to the exercise of the Board's functions of arranging for the provision of services for the purposes of the health service in England^(a), in particular—
 - (i) its functions under sections 4 (high security psychiatric services)^(b), 83 (primary medical services)^(c), 99 (primary dental services)^(d), 115 (primary ophthalmic services)^(e), and 126 (arrangements for pharmaceutical services)^(f) of the 2006 Act;
 - (ii) its functions under regulations under section 3B(1) of that Act (Secretary of State's power to require Board to commission services)^(g);
 - (iii) functions exercisable by the Board pursuant to arrangements under section 7A of that Act (exercise of Secretary of State's public health functions)^(h); and
 - (iv) its functions by virtue of regulations under section 117(2E) of the Mental Health Act 1983 (after-care)⁽ⁱ⁾;
- (b) a CCG in the case of a technology appraisal recommendation that applies to the exercise of the CCG's functions of arranging for the provision of services for the purposes of the health service in England^(j), in particular—

(a) Section 1H of the 2006 Act sets out the general functions of the Board.

(b) Section 4(1) is amended by section 16 of the Act.

(c) Section 83 is amended by paragraph 30 of Schedule 4 to the Act.

(d) Section 99 is amended by paragraph 42 of Schedule 4 to the Act.

(e) Section 115 is amended by paragraph 54 of Schedule 4 to the Act.

(f) Section 126 is amended by sections 213(7) and 220(7) of, and paragraph 63 of Schedule 4 to, the Act.

(g) Section 3B is inserted into the 2006 Act by section 15 of the Act. See Part 3 of S.I. 2012/2996 for services to be commissioned by the Board.

(h) Section 7A is inserted into the 2006 Act by section 22 of the Act. See section 13Z4(2) of that Act (interpretation) as regards functions of the Secretary of State that are exercisable by the Board.

(i) 1983 c. 20. Subsection (2E) is inserted by section 40(3) of the Act. See regulation 15 of S.I. 2012/2996 for circumstances in which a duty may be imposed on the Board.

(j) Section 1I of the 2006 Act sets out general functions of CCGs.

- (i) its functions under sections 3 (duties of clinical commissioning groups as to commissioning certain health services)(a) and 3A (power of clinical commissioning groups to commission certain health services)(b) of, and paragraph 9 of Schedule 1 (provision of vehicles for disabled persons)(c) to, the 2006 Act;
 - (ii) functions exercisable by a CCG pursuant to arrangements under section 7A of that Act(d);
 - (iii) its functions under section 117(2), or by virtue of regulations under section 117(2E), of the Mental Health Act 1983(e); or
- (c) a local authority in the case of a technology appraisal recommendation that applies to the provision of public health services which the local authority must arrange—
- (i) for the purpose of the exercise of its functions under or by virtue of section 2B (functions of local authorities and Secretary of State as to improvement of public health)(f), 6C(1) or (3) (regulations as to the exercise by local authorities of certain public health functions)(g) and 111 (dental public health)(h) of, and Schedule 1 (further provision about the Secretary of State and services under this Act)(i) to, the 2006 Act; or
 - (ii) in pursuance of arrangements under section 7A of that Act.
- (8) The duty of a relevant health body in paragraph (6) must be taken to require that—
- (a) where the Board is a relevant health body, the Board must apply such amounts of the sums paid to it under section 223B(1) of the 2006 Act (funding of the Board)(j) as may be required to enable the Board to comply with the recommendation;
 - (b) where a CCG is a relevant health body, the CCG must apply such amounts of the sums paid to it under section 223G(1) of the 2006 Act (means of meeting expenditure of clinical commissioning groups out of public funds)(k) as may be required to enable the CCG to comply with the recommendation; or
 - (c) where a local authority is a relevant health body, the local authority must apply such amounts of the sums paid to it under section 31 of the Local Government Act 2003(l) (power to pay grant) for the purpose of funding the performance of its functions under section 2B or 111 of, or paragraphs 1 to 7B or 13 of Schedule 1 to, that Act, as may be required to enable the local authority to comply with the recommendation.
- (9) NICE must establish a procedure for the appraisal of health technologies, and must consult such persons as it considers appropriate in establishing the procedure.
- (10) The procedure must include arrangements for NICE to consult such persons with an interest in the appraisal of a health technology that is the subject of a direction referred to in paragraph (1)(a) as it considers appropriate.
- (11) In the circumstances described in paragraph (5)—

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- (a) Section 3 of the 2006 Act is amended by section 13 of the Act. *See* regulation 4 of, and Schedule 1 to, S.I. 2012/2996 for provision on additional persons for whom a CCG has responsibility.
 - (b) Section 3A of the 2006 Act is inserted by section 14 of the Act. *See* regulation 4 of, and Schedule 1 to, S.I. 2012/2996 for provision on additional persons for whom a CCG has responsibility.
 - (c) Paragraph 9 of Schedule 1 to the 2006 Act is amended by section 17(2) and (10)(b) of the Act.
 - (d) *See* section 14Z24(2) of the 2006 Act (interpretation) as regards functions of the Secretary of State that are exercisable by a CCG.
 - (e) Section 117 is amended by section 40(1) to (6) of the Act. *See* regulation 14 of S.I. 2012/2996 for circumstances in which the duty imposed by section 117(2) may instead be imposed on another CCG.
 - (f) Section 2B is inserted into the 2006 Act by section 12 of the Act.
 - (g) Section 6C is inserted into the 2006 Act by section 18(1) of the Act.
 - (h) Section 111 is amended by section 29(1) and (2) of the Act.
 - (i) Paragraphs 1 to 7 of Schedule 1 are amended by section 17(2) to (8) of the Act. Paragraphs 7A and 7B were inserted into the Schedule by section 143(1) of the Health and Social Care Act 2008 (c. 14), and are amended by section 17(2), (7) and (8) of the Act. Paragraph 13 is substituted by sections 17(2) and (13) of the Act.
 - (j) Section 223B is inserted into the 2006 Act by section 24 of the Act.
 - (k) Section 223G is inserted into the 2006 Act by section 27 of the Act.
 - (l) 2003 c. 26.

(a) pursuant to paragraph (4), the consultation referred to in paragraph (10) must include consultation about the appropriate period that may be specified in a technology appraisal recommendation; and

(b) the Secretary of State and the Board must be consulted as to the appropriate period.

(12) NICE must publish a technology appraisal recommendation in such form and manner and at such time as NICE considers appropriate.

(13) NICE must keep under review and may revise as it considers appropriate a technology appraisal recommendation.

(14) The Secretary of State must not give a direction under paragraph (1)(a) about the substance of a technology appraisal recommendation.

NICE highly specialised technology recommendations

8.—(1) NICE may make a highly specialised technology recommendation—

(a) in relation to a highly specialised health technology identified in a direction given by the Secretary of State;

(b) that recommends that the Board, in the exercise of the Board's function to arrange for the provision as part of the health service of services specified in regulations made under section 3B of the 2006 Act^(a), provide funding within a specified period to ensure that the highly specialised health technology can be made available for the purposes of treatment of patients.

(2) NICE must specify in a highly specialised technology recommendation the period within which the Board must comply with the recommendation in paragraph (1)(b).

(3) The period in paragraph (2) must be a period that begins on the date the recommendation is published by NICE and ends on a date 3 months from that date, unless paragraph (4) applies.

(4) In the circumstances described in paragraph (5), if NICE considers it appropriate, NICE must specify a longer period.

(5) The circumstances referred to in paragraphs (4) and (10) are—

(a) the highly specialised health technology cannot be appropriately administered until—

(i) training is,

(ii) certain health services infrastructure requirements including goods, materials or other facilities are, or

(iii) other appropriate health services resources, including staff, are, in place; or

(b) the highly specialised health technology is not yet available in England.

(6) The Board must comply with a highly specialised technology recommendation.

(7) The duty of the Board in paragraph (6) must be taken to require that the Board apply such amounts of the sums paid to it under section 223B(1) of the 2006 Act as may be required to enable the Board to comply with the paragraph (1)(b) recommendation.

(8) NICE must establish a procedure for the appraisal of highly specialised health technologies, and must consult such persons as it considers appropriate in establishing the procedure.

(9) The procedure must include arrangements—

(a) for NICE to consult such persons with an interest in the appraisal of a highly specialised health technology that is the subject of a direction referred to in paragraph (1)(a) as it considers appropriate; and

(b) for the Board to be consulted as such a person.

(10) In the circumstances described in paragraph (5)—

(a) See Part 3 of S.I. 2012/2996 for services to be commissioned by the Board.

(a) pursuant to paragraph (4), the consultation referred to in paragraph (9)(a) must include consultation about the appropriate period that may be specified in a highly specialised technology recommendation; and

(b) the Secretary of State and the Board must be consulted as to the appropriate period.

(11) NICE must publish a highly specialised technology recommendation in such form and manner and at such time as NICE considers appropriate.

(12) NICE must keep under review and may revise as it considers appropriate a highly specialised technology recommendation.

(13) The Secretary of State must not give a direction under paragraph (1)(a) about the substance of a highly specialised technology recommendation.

NICE recommendations: appeals

9.—(1) A person aggrieved by a recommendation described in paragraph (2) may bring an appeal against the recommendation on grounds described in paragraph (3).

(2) A recommendation against which an appeal may be brought is—

- (a) a technology appraisal recommendation, or
- (b) a highly specialised technology recommendation.

(3) The grounds on which an appeal may be brought are that—

- (a) in making the assessment that preceded the recommendation, NICE—
 - (i) failed to act fairly, or
 - (ii) exceeded its powers; or
- (b) the recommendation is unreasonable in the light of the evidence submitted to NICE.

NICE recommendations: appeal panel

10.—(1) The appeal panel by which an appeal brought under regulation 9 is to be heard must—

- (a) consist of members appointed by NICE whose appointment has been agreed by the Secretary of State;
- (b) contain a majority of members who are not members or employees of NICE; and
- (c) include—
 - (i) a member who has experience in the life sciences industry;
 - (ii) a member who is a patient or carer or member of an organisation that represents patients or carers; and
 - (iii) a member who is engaged in the provision of health care^(a) in the health services.

(2) A chair of the appeal panel must be appointed by NICE—

- (a) from amongst the members who are not members or employees of NICE; and
- (b) only if the appointment as a chair has been agreed by the Secretary of State.

Arrangements for holding appeals

11.—(1) NICE must make arrangements for the holding of appeals.

(2) The arrangements must include procedures for dealing with conflicts of interests or potential conflicts of interests of members or potential members of an appeal panel.

(a) “Health care” is defined in section 240(4) of the Act.

Training

12.—(1) NICE has the function of providing, or facilitating the provision of, training in connection with any matter concerning or connected with the provision of—

- (a) NHS services;
- (b) public health services; or
- (c) social care in England.

(2) NICE has power to impose a charge for or in connection with the provision, or the facilitation of the provision, of training.

(3) A charge imposed pursuant to paragraph (2) may be calculated as NICE considers—

- (a) appropriate to enable NICE to recover the cost of providing the service; or
- (b) to be the appropriate commercial basis.

Advisory services

13.—(1) NICE may give advice to persons (whether or not in the United Kingdom) in relation to any matter concerning or connected with—

- (a) the provision of health care;
- (b) the protection or improvement of public health; or
- (c) the provision of social care.

(2) The persons mentioned in paragraph (1) include—

- (a) persons concerned or connected with the life sciences industry;
- (b) persons otherwise concerned or connected with a health technology or a highly specialised health technology;
- (c) a devolved authority;
- (d) a foreign government; or
- (e) an international body or organisation.

(3) NICE may impose a charge for or in connection with the giving of advice pursuant to paragraph (1).

(4) NICE must calculate a charge imposed on a devolved authority so as to enable NICE to recover no more than the cost of providing the advice.

(5) NICE may calculate a charge imposed on any other person on the basis NICE considers to be the appropriate commercial basis.

NICE's charter

14.—(1) NICE must publish the charter^(a) before 1st July 2013.

(2) NICE may include in the charter such information as it considers appropriate but must include information on—

- (a) the procedures it establishes for carrying out its functions; and
- (b) the consultation it undertakes in the establishment of its procedures and in the carrying out of its functions.

(3) NICE may revise the charter when it considers it appropriate to do so but must review the charter to consider whether it should be revised at least once in any review period.

(4) A review period referred to in paragraph (3) is—

- (a) the period of 3 years beginning with the day on which the charter is published, and

(a) See section 242 of the Act for provisions about NICE's charter.

- (b) each subsequent period of 3 years.

Transitional provision – directions: recommendations, guidelines and information

15.—(1) Paragraph (3) applies where, before the relevant date, the Institute, in connection with the promotion of clinical excellence and the effective use of available resources in the health service, has been directed by the Secretary of State^(a) to—

- (a) develop guidelines providing advice on good practice in the management of such diseases and conditions as may be notified by the Secretary of State;
- (b) provide such information on the implementation of the Institute’s recommendations and guidelines to persons employed in activities connected with the health service as may be conducive to their efficiency in relation to that employment;
- (c) include in its recommendations and guidelines guidance on clinical audit criteria;
- (d) disseminate through an appropriate range of media its recommendations and guidelines to the health service and general public;
- (e) look into and consider, for the purpose of advising the Secretary of State with regard to possible improvements in the provision of health services and in the effective use of available resources, such matters as were notified to it by the Secretary of State;
- (f) consider all interventional procedures notified to it;
- (g) identify any interventional procedure notified to it for which an assessment by the Institute as to whether it is safe and efficacious for use in the health service is unnecessary;
- (h) identify any interventional procedure notified to it otherwise than by the Secretary of State for which a comprehensive review of the evidence is required to enable the Institute to evaluate the procedure for the purposes of its recommendations or guidelines; and to evaluate its safety and efficacy for the purposes of use in the health service, and issue guidance to the health service on the use of the procedure;
- (i) assess the extent to which any interventional procedure notified to the Institute, other than one for which an assessment by the Institute is unnecessary, is safe and efficacious for use in the health service, and issue guidance to the health service on the use of the procedure;
- (j) subject to the approval of the Secretary of State, consider, and, as appropriate, endorse guidance prepared by other bodies concerning the clinical benefits of health care interventions^(b) and good practice in the management of diseases and other conditions affecting health; or
- (k) exercise any similar function of the Secretary of State relating to the health service, other than a function referred to in paragraph (3) or regulations 16 to 23.

(2) Paragraph (3) applies where, before the relevant date, the Institute, in connection with the promotion of excellence in public health provision and promotion and the effective use of resources available in the health service and other available public funds, has been directed by the Secretary of State^(c) to—

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- (a) See paragraphs 2(1), (3) and (4) of the Directions and Consolidating Directions to the National Institute for Health and Clinical Excellence 2005, signed on 31st March 2005 (the NICE 2005 Directions), as amended by the Directions to the National Institute for Health and Clinical Excellence 2007, signed on 13th March 2007 (the 2007 Directions), Further Directions to the National Institute for Health and Clinical Excellence 2009, signed on 30th April 2009 (the 2009 Directions), and the National Institute for Health and Clinical Excellence (Amendment) Directions 2012, signed on 30 th March 2012 (the 2012 Directions). Copies of the Directions can be obtained from the NICE Sponsor team, Quarry House, Quarry Hill, Leeds, LS2 7UE.
 - (b) See the Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) which came into force on 1st July 2003 (the Funding Directions). The Funding Directions can be viewed at http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Legislation/DirectionsfromtheSecretaryofState/DH_4075685.
 - (c) See paragraph 2(2) of the NICE 2005 Directions.

- (a) develop, maintain and disseminate an evidence-base for effective public health action on health improvement and the reduction of inequalities in health;
- (b) provide guidance on the development and setting of standards for public health and health promotion programmes and practice and support their implementation;
- (c) provide guidance on the means for improving the capability and capacity of organisations, systems and the wider public health workforce to deliver health improvement and reduce inequalities in health; or
- (d) disseminate through an appropriate range of media, the guidance described in subparagraphs (b) and (c).

(3) Where this paragraph applies, on and after the relevant date, NICE must treat the direction as if the direction had been given by the Secretary of State—

- (a) in the case of a matter concerning or connected with the provision of NHS services, under regulation 5(2); or
- (b) in the case of a matter concerning or connected with the provision of public health services, under regulation 5(3).

Transitional provision – directions: technology appraisal guidance

16.—(1) Where, before the relevant date, the Institute, in connection with the promotion of clinical excellence and the effective use of available resources in the health service, has been directed by the Secretary of State to appraise the clinical benefits and costs of such health care interventions as may have been notified by the Secretary of State, and to make recommendations(a), paragraph (2) applies.

(2) Where this paragraph applies, on and after the relevant date, NICE must treat the direction as a direction given by the Secretary of State under regulation 7(1)(a).

Transitional provision – Appeal Panels

17.—(1) Where the Institute has made arrangements for an appeal, on the application of a person aggrieved by a recommendation made by the Institute on the grounds that the Institute—

- (a) failed to act fairly,
- (b) exceeded its powers, or
- (c) formulated guidance which cannot reasonably be justified in the light of the evidence submitted(b),

but has not determined the application before the relevant date, paragraph (2) applies.

(2) Where this paragraph applies, on and after the relevant date—

- (a) any Appeal Panel that has been appointed by the Institute to determine the application of a person aggrieved is to be treated as an appeal panel constituted in accordance with regulation 10; and
- (b) NICE must make arrangements in accordance with regulation 11 for the determination of the application.

Transitional provision – directions: instruction

18.—(1) Where, before the relevant date, the Institute has been directed to provide the instruction described in paragraphs (2) and (3), on and after the relevant date, NICE must provide the instruction as if it were training that NICE has the function of providing or facilitating the provision of under regulation 12(1)(a).

(a) See paragraph 2(1)(a) of the NICE 2005 Directions.

(b) See paragraph 5 of the NICE 2005 Directions, as amended by the 2007 Directions.

(2) The instruction referred to in paragraph (1) is the provision by the Institute of education, training and development to support the safe and effective use of medicines^(a).

(3) The education, training and development referred to in paragraph (2) includes—

- (a) instruction on the implementation of the Institute’s recommendations and guidelines to persons employed in activities connected with the health service;
- (b) supporting the implementation of good practice guidance;
- (c) developing educational resources and materials; and
- (d) organising and delivering a national education and training event programme.

(4) Regulation 12(2) and (3) does not apply in the case of training provided pursuant to paragraph (1).

Transitional provision – procedures: recommendations, guidelines, information or instruction

19.—(1) Anything done by the Institute before the relevant date, in pursuance of a direction given by the Secretary of State described in regulation 15(1) or (2), is to be treated, on and after the relevant date, as having been done by NICE in pursuance of a direction given by the Secretary of State—

- (a) in the case of a matter concerning or connected with the provision of NHS services, under regulation 5(2); or
- (b) in the case of a matter concerning or connected with the provision of public health services, under regulation 5(3).

(2) A procedure established or published by the Institute for the giving of advice or guidance, the provision of information or the making of recommendations by the Institute before the relevant date, is to be treated, on and after the relevant date, as if it were a procedure established or published by NICE in accordance with regulation 5(4).

(3) Consultation with any person undertaken by the Institute for the establishment of a procedure for the giving of advice or guidance, the provision of information or the making of recommendations before the relevant date, is to be treated, on and after the relevant date, as if it were consultation for the establishment of a procedure carried out by NICE in accordance with regulation 5(5).

(4) The publication or dissemination by the Institute of advice, guidance, information or recommendations given, provided or made by the Institute, including through its website under the title, “NHS Evidence”^(b), before the relevant date, is to be treated, on and after the relevant date, as publication or dissemination by NICE in accordance with regulation 5(6).

(5) In this regulation, “recommendations” does not include a recommendation made by the Institute in relation to a health care intervention in a Technology Appraisal Guidance issued by the Institute as described in regulation 20(1).

Transitional provision – procedures: health care interventions

20.—(1) A recommendation made by the Institute in relation to a health care intervention in a Technology Appraisal Guidance issued by the Institute before the relevant date, is to be treated, on and after the relevant date, as if it were a technology appraisal recommendation made by NICE pursuant to regulation 7(1).

(2) A procedure for the appraisal by the Institute of the clinical benefits and costs of a health care intervention, in connection with the promotion of clinical excellence and the effective use of available resources in the health service, established by the Institute before the relevant date, is to

(a) See paragraph 2(1)(c) and (12)(c) of the NICE 2005 Directions, as amended by the 2012 Directions.

(b) “NHS Evidence” can be viewed at www.evidence.nhs.uk.

be treated, on and after the relevant date, as a procedure for the appraisal of a health technology pursuant to regulation 7(9).

(3) Anything done by the Institute by way of appraisal of the clinical benefits and costs of a health care intervention, in connection with the promotion of clinical excellence and the effective use of available resources in the health service, before the relevant date, is to be treated, on and after the relevant date, as done in accordance with a procedure established by NICE pursuant to regulation 7(9).

(4) Consultation undertaken by the Institute for the appraisal by the Institute of the clinical benefits and costs of a health care intervention, in connection with the promotion of clinical excellence and the effective use of available resources in the health service, before the relevant date, is to be treated, on and after the relevant date, as consultation undertaken by NICE in accordance with arrangements included in the procedure established pursuant to regulation 7(9) as set out in regulation 7(10).

(5) The issuance by the Institute of a Technology Appraisal Guidance to the health service on the use of a health care intervention before the relevant date, is to be treated, on and after the relevant date, as publication of a technology appraisal recommendation by NICE in accordance with regulation 7(12).

Transitional provision – appeal arrangements

21. Arrangements for holding appeals made by the Institute before the relevant date, are to be treated, on and after the relevant date, as arrangements for the holding of appeals made pursuant to regulation 11.

Transitional provision – procedures: instruction

22. Anything done by the Institute before the relevant date, in pursuance of a direction given by the Secretary of State referred to in regulation 18(1), is to be treated, on and after the relevant date, as having been done by NICE under regulation 12(1)(a), but regulation 12(2) and (3) does not apply in the case of training provided pursuant to regulation 18(1).

Transitional provision - charter

23. Preparation of a charter by the Institute before the relevant date, is to be treated, on and after the relevant date, as if it were preparation by NICE for the purposes of publishing the charter pursuant to regulation 14(1).

PART 3

The Health and Social Care Information Centre

Interpretation

24. In this Part—

“the Authority” means the Special Health Authority known as the Health and Social Care Information Centre^(a);

“confidential information” has the same meaning as in section 263(2) of the Act;

“confidential patient information” means patient information where—

(a) the identity of the individual in question is ascertainable—

(a) The Health and Social Care Information Centre was established by the Health and Social Care Information Centre (Establishment and Constitution) Order 2005, S.I. 2005/499 and abolished by section 276 of the Act, which is to come into force on 1st April 2013 (*see* S.I. 2013/160 (C. 9)).

- (i) from that information, or
 - (ii) from that information and other information which is in the possession of, or likely to come into the possession of, the person processing that information, and
- (b) that information was obtained or generated by a person who, in the circumstances, owed an obligation of confidence to that individual(a).

“the 2005 Directions” means the Health and Social Care Information Centre Directions 2005(b);

“indicator specification” means an indicator specification prepared by the Information Centre in accordance with regulation 28;

“the Information Centre” means the Health and Social Care Information Centre established by section 252 of the Act;

“the library” means the library of quality indicators(c) described in regulation 25(2)(b);

“medical performers list” means a list of medical practitioners maintained by the Board in accordance with regulations made under section 91 of the 2006 Act;

“methodology” may include—

- (a) mathematical calculations or formulae to be applied to data,
- (b) rules to be applied to data to organise the data appropriately,
- (c) other statistical processes including risk adjustment to identify and adjust for variation in outcomes of interest that stem from differences in risk factors, or
- (d) details of any relevant information standard(d) that must be adhered to;

“the NHS Central Register” means the record of all persons—

- (a) who before the relevant date, were or had been registered with a provider of primary medical services in England for the purposes of receiving such services under the 2006 Act(e); and
- (b) who were not or had not been so registered, but who were at any time before 1st April 2004, registered with a provider of general medical services in England for the purposes of receiving such services(f);

“patient information” means—

- (a) information (however recorded) which relates to the physical or mental health or condition of an individual, to the diagnosis of the individual’s condition or to the care or treatment of the individual, and
- (b) information (however recorded) which is to any extent derived, directly or indirectly, from such information,

whether or not the identity of the individual in question is ascertainable from the information(g);

“prescribing number” means the individual number issued by the Information Centre in accordance with regulation 31 and used in connection with—

- (a) prescribing by a general medical practitioner,
- (b) the management and monitoring of such prescribing, and
- (c) other purposes connected with the health services in England;

(a) See section 251(11) of the 2006 Act.

(b) The Health and Social Care Information Centre Directions 2005 (the 2005 Directions) were signed on 24th March 2005. The 2005 Directions have been amended by the Health and Social Care Information Centre (Amendment) Directions 2008 (the 2008 Directions), signed on 31st March 2008. Copies of the 2005 Directions and the 2008 Directions can be obtained from External Relations, Department of Health, Zone 5B, Skipton House, London SE1 6LH.

(c) “Quality indicator” is defined in section 268(3) of the Act.

(d) See section 250 of the Act for the definition of, and other provision about, information standards.

(e) See sections 83 and 276 of the 2006 Act for the meaning of “primary medical services” under that Act.

(f) See section 84 of the 2006 Act.

(g) See section 251(10) of the 2006 Act.

“proposer” means a person referred to in regulation 26(2).

Database of quality indicators

25.—(1) The Information Centre must establish, maintain and publish a database of quality indicators in relation to the provision of health services^(a) and adult social care^(b) in England.

(2) The database is to consist of—

- (a) a repository that contains—
 - (i) applications for a quality indicator to be included in the library,
 - (ii) information related to an application,
 - (iii) information about the assessment of an application, and
 - (iv) information about a quality indicator that has not been assessed as suitable for inclusion in the library; and
- (b) a library consisting of assured quality indicators that have been assessed as suitable for inclusion in the library.

(3) The Information Centre must—

- (a) establish procedures for the assessment of a quality indicator; and
- (b) arrange for each quality indicator published in the library to be periodically reviewed.

Application for a quality indicator to be included in the library

26.—(1) Any person (whether or not in the United Kingdom) may apply to the Information Centre to have a quality indicator included in the library.

(2) The Information Centre may request a person who has applied pursuant to paragraph (1) (“the proposer”) to provide details in the application of—

- (a) why the indicator is needed;
- (b) persons who will use, or benefit from the use of, the indicator;
- (c) the methodology to be used in constructing the indicator;
- (d) the data sources for the data in relation to which the methodology will be applied; or
- (e) how the quality indicator is to be published, which may include—
 - (i) the form, manner and timing of publication,
 - (ii) the person who will publish the indicator, or
 - (iii) any other matter related to publication of the indicator.

(3) The Information Centre may request the proposer to provide, or do, any other thing that the Information Centre considers is necessary or expedient to enable the Information Centre to carry out its functions in relation to a quality indicator.

(4) The Information Centre need not make arrangements under regulation 27(1) if the proposer fails to comply with a request made pursuant to paragraph (2) or (3).

(5) The Information Centre must publish guidance for the benefit of proposers or potential proposers on the making of an application pursuant to paragraph (1).

Assessment of an application for a quality indicator to be included in the library

27.—(1) The Information Centre must make arrangements for persons identified by the Secretary of State or the Board in writing to assess, and, if appropriate, approve, an application made pursuant to regulation 26, unless regulation 26(4) applies.

(a) “Health services” is defined in section 253(3) of the Act.

(b) “Adult social care” is defined in section 253(3) of the Act.

- (2) A person mentioned in paragraph (1) must be—
- (a) a peer reviewer with knowledge relevant to the assessment of the application; or
 - (b) a statistical or analytical expert with knowledge of the methodology described in an application; or
 - (c) a person, who may be a member of staff of the Information Centre, able to advise the Information Centre in connection with the governance or strategic management of the contents of the library.
- (3) The Information Centre may request that, where appropriate, the persons mentioned in paragraph (1) make recommendations for the purpose of enabling a proposer to revise the proposer's application.
- (4) The Information Centre must advise a proposer about any recommendations made by persons pursuant to paragraph (3).
- (5) The Information Centre may provide a proposer with advice and guidance generally about the application.

Publication following assessment

28.—(1) When the assessment of an application made pursuant to regulation 26(1) has been completed, the Information Centre must prepare an indicator specification.

- (2) An indicator specification may include—
- (a) the purpose of the quality indicator, in particular what it is to be used for;
 - (b) the sources of data to be used in producing the quality indicator;
 - (c) the methodology to be used in constructing the quality indicator;
 - (d) guidance for interpreting the quality indicator, including about criteria that indicate a better quality outcome;
 - (e) the appropriate frequency for the use of the quality indicator;
 - (f) the arrangements for publication of the quality indicator;
 - (g) any concerns expressed by the persons referred to in regulation 27(1) about—
 - (i) the quality of the data sources mentioned in sub-paragraph (b); or
 - (ii) the methodology;
 - (h) the arrangements for review of the quality indicator to be carried out by the Information Centre or another person; or
 - (i) any other information that the Information Centre considers relevant.
- (3) The Information Centre must publish in the repository referred to in regulation 25(2)(a)—
- (a) the application referred to in regulation 26(2);
 - (b) any recommendation made pursuant to regulation 27(3); and
 - (c) the indicator specification prepared pursuant to paragraph (1).
- (4) The Information Centre may make arrangements to ensure that an obligation of confidence owed in relation to confidential patient information published, or confidential information that is published, in the database of quality indicators is respected.

Publication in the library

29.—(1) If a quality indicator is approved for inclusion in the library, the Information Centre must arrange for the publication in the library on its website of—

- (a) the quality indicator; and
- (b) the indicator specification for the quality indicator.

(2) The Information Centre must publish with the quality indicator a mark that indicates the assured level of confidence that the Information Centre has in the quality indicator as a quality indicator.

Review and revision of a quality indicator

30.—(1) When, pursuant to its duty in regulation 25(3)(b), the Information Centre arranges for the review of a quality indicator published in the library, it must make arrangements it considers appropriate for updating or otherwise revising the quality indicator.

(2) The arrangements must include arrangements for updating or otherwise revising the indicator specification.

(3) The Information Centre may provide advice to the proposer of the quality indicator in relation to the updating or other revision of the indicator.

Identification of GPs

31.—(1) The Board may request the Information Centre to provide a prescribing number in respect of a general medical practitioner^(a) whose name is included in a medical performers list.

(2) Where the Board has made a request pursuant to paragraph (1), the Information Centre must carry out checks to verify the identity of the general medical practitioner.

(3) The Information Centre need not comply with a request made pursuant to paragraph (1) if the Board fails to provide information that the Information Centre considers is necessary to enable it to carry out checks to verify the identity of the general medical practitioner.

(4) The checks to verify identity referred to in paragraph (2) may include—

- (a) the full name of the general medical practitioner; and
- (b) the reference number shown against the name of the general medical practitioner in the General Practitioner Register kept by the General Medical Council.

(5) If, having carried out the checks referred to in paragraph (2), the Information Centre considers it appropriate to do so, the Centre must—

- (a) assign a prescribing number to the general medical practitioner; and
- (b) issue the prescribing number to the Board.

Powers of Secretary of State or Board to give directions

32.—(1) The Secretary of State or the Board may give directions to the Information Centre requiring the Centre to exercise such systems delivery functions of the Secretary of State or (as the case may be) the Board as may be specified in the direction.

(2) The giving of a direction under paragraph (1)—

- (a) by the Secretary of State, may include provision about payments by the Secretary of State to the Information Centre for things done in the exercise of the function in respect of which the direction is given;
- (b) by the Board, must permit the Information Centre to charge the Board a reasonable fee in respect of the cost of complying with the direction.

(3) The giving of a direction under paragraph (1) does not prevent the Secretary of State or (as the case may be) the Board from exercising the function in respect of which the direction is given.

(a) “General medical practitioners” is defined in section 269(2) of the Act.

Transitional provision – the Information Centre

33.—(1) An application submitted to the Authority to have a quality indicator included in a library of quality indicators published by the Authority^(a) before the relevant date, is to be treated, on and after the relevant date, as an application made pursuant to regulation 26.

(2) Where, before the relevant date, arrangements have been made for persons identified by the Secretary of State to assess and if appropriate, approve, an application described in paragraph (1) for inclusion in the library of quality indicators described in that paragraph, those persons are to be treated in respect of that application as persons identified by the Secretary of State or the Board pursuant to regulation 27(1) and (2).

(3) Any quality indicator described in an application to which paragraph (1) applies which is approved for inclusion in a library of quality indicators described in paragraph (1) is to be treated, on and after the relevant date, as if it were a quality indicator approved for inclusion in the library referred to in regulation 29 and to which regulations 29 and 30 apply.

(4) Where, before the relevant date, the Authority—

(a) has received an application from a Primary Care Trust for a prescribing number to be issued to the Primary Care Trust in respect of a general medical practitioner whose name is included in a performers list prepared by the Primary Care Trust; but

(b) has not issued, or assigned, a prescribing number in respect of the general medical practitioner to whom the application relates,

the Information Centre shall treat the application as a request from the Board pursuant to regulation 31(1) and regulation 31(2) to (5) shall apply.

(5) Anything done by the Authority before the relevant date, pursuant to a direction of the Secretary of State in the 2005 Directions in relation to a database of quality indicators, is to be treated, on and after the relevant date, as having been done by the Information Centre in pursuance of its functions in relation to the database of quality indicators described in regulation 25.

(6) A recommendation made by persons identified by the Secretary of State to assess and if appropriate, approve, an application described in paragraph (1) for inclusion in a library of quality indicators described in that paragraph before the relevant date, is to be treated, on and after the relevant date, as a recommendation for the purpose of enabling a proposer to revise the proposer's application made pursuant to regulation 27(3).

(7) A quality indicator included in a library of quality indicators published by the Authority before the relevant date, is to be treated, on and after the relevant date, as a quality indicator to which regulations 25, 29 and 30 apply.

Signed by authority of the Secretary of State for Health.

Earl Howe
Parliamentary Under-Secretary of State,
Department of Health

11th February 2013

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision in relation to the National Institute for Health and Care Excellence (“NICE”) (established under Part 8 of the Health and Social Care Act 2012 (c. 7) (“the Act”)) and the Health and Social Care Information Centre (“the Information Centre”) (established under Chapter 2 of Part 9 of the Act).

Part 2 makes provision in relation to NICE, which is established by section 232 of the Act.

(a) See paragraph 2(h) of the 2005 Directions.

Regulation 3 provides for procedures for conflicts of interests of members of NICE.

Section 234 of the Act (quality standards) enables the Secretary of State or the National Health Service Commissioning Board (“the Board”) to direct NICE to prepare a quality standard. Regulation 4 confers powers on NICE for the supply of a quality standard to a devolved authority or other person and to make adjustments to, and impose a charge in connection with, such supply.

Regulation 5 confers functions on NICE in relation to the giving of advice or guidance, provision of information or making of recommendations about any matter concerning or connected with the provision of NHS services (exercisable only on the direction of the Secretary of State or the Board), or public health services or social care in England (exercisable only on the direction of the Secretary of State). The Secretary of State or the Board may give directions about the exercise of a function (regulation 5(2)(b) and, in the case of the Secretary of State, (3)(b)), but must not give a direction about the substance of advice, guidance, or a recommendation (regulation 5(8) and (9)).

Regulation 6 provides powers for NICE to be able to impose a charge for or in connection with the functions conferred by regulation 5, other than on the Secretary of State or a person identified in a direction of the Secretary of State.

Regulation 7 makes provision for NICE to make a technology appraisal recommendation, in relation to a health technology identified in a direction of the Secretary of State, that recommends that the Board, a clinical commissioning group or a local authority arranging for the provision of services for the purposes of the health service, provide funding to ensure that the health technology can be made available for the purposes of treatment of patients. The NICE technology appraisal recommendation must be complied with normally within 3 months of publication of the recommendation (regulation 7(3)).

Regulation 8 makes provision for NICE to make a highly specialised technology recommendation in relation to a highly specialised health technology identified in a direction of the Secretary of State, that recommends that the Board provide funding to ensure that the highly specialised technology can be made available for the purposes of treatment of patients, normally within 3 months of publication of the highly specialised technology recommendation.

Regulations 9 to 11 make provision for appeals against a technology appraisal recommendation or a highly specialised technology recommendation.

Regulation 12 confers functions on NICE in relation to the provision of training in connection with the provision of NHS services, public health services or social care in England.

Regulation 13 provides for NICE to be able to give advice to persons (whether or not in the United Kingdom) on any matter concerning or connected with the provision of health care or social care or the protection or improvement of public health, and to impose a charge for or in connection with the giving of the advice.

Regulation 14 makes provision in relation to NICE’s charter.

Regulations 15 to 23 make transitional provision for the continuation of work in progress, or procedures being undertaken, by NICE’s predecessor, the Special Health Authority, the National Institute for Health and Clinical Excellence, immediately before 1st April 2013.

Part 3 provides for functions of the Information Centre, established by section 252 of the Act.

Regulations 25 to 30 provide for the establishment of a database of quality indicators in relation to the provision of health services and adult social care in England. A quality indicator is defined in section 268(3) of the Act to mean a factor by reference to which performance in the provision of services or care can be measured. The database is to consist of a repository of applications for a quality indicator and related information (regulation 25(2)(a)) and a library of assured quality indicators (regulation 25(2)(b)).

Regulation 31 provides for the Information Centre to have functions in relation to the assignment of a prescribing number to a general medical practitioner.

Regulation 32 confers systems delivery functions on the Information Centre that are exercisable on the direction of the Secretary of State or the Board. The giving of a direction does not prevent the Secretary of State or the Board from exercising the function in respect of which the direction is given (regulation 32(3)).

Regulation 33 makes transitional provision for the continuation of procedures being undertaken in relation to a quality indicator or prescribing number by the predecessor Special Health Authority, the Health and Social Care Information Centre, immediately before 1st April 2013.

A full impact assessment has been produced in relation to the provisions of the Act, and a copy is available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_123583. Pages 126 and 127 of Annex E to the assessment contains information relevant to the establishment of NICE and pages 136 and 137 contain information relevant to the establishment of the Information Centre. No separate impact assessment has been produced in relation to Parts 2 or 3 of these Regulations as the Parts have no impact on the private sector or civil society organisations.

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