
STATUTORY INSTRUMENTS

2013 No. 259

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

PART 2

The National Institute for Health and Care Excellence

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⁽¹⁾, in particular—

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

- (i) its functions under sections 4 (high security psychiatric services)(**2**), 83 (primary medical services)(**3**), 99 (primary dental services)(**4**), 115 (primary ophthalmic services)(**5**), and 126 (arrangements for pharmaceutical services)(**6**) 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)(**7**);
 - (iii) functions exercisable by the Board pursuant to arrangements under section 7A of that Act (exercise of Secretary of State’s public health functions)(**8**); and
 - (iv) its functions by virtue of regulations under section 117(2E) of the Mental Health Act 1983 (after-care)(**9**);
- (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(**10**), in particular—
- (i) its functions under sections 3 (duties of clinical commissioning groups as to commissioning certain health services)(**11**) and 3A (power of clinical commissioning groups to commission certain health services)(**12**) of, and paragraph 9 of Schedule 1 (provision of vehicles for disabled persons)(**13**) to, the 2006 Act;
 - (ii) functions exercisable by a CCG pursuant to arrangements under section 7A of that Act(**14**);
 - (iii) its functions under section 117(2), or by virtue of regulations under section 117(2E), of the Mental Health Act 1983(**15**); 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)(**16**), 6C(1) or (3) (regulations as to the exercise by local authorities of certain public health functions)(**17**) and 111 (dental public health)(**18**) of, and Schedule 1 (further provision about the Secretary of State and services under this Act)(**19**) to, the 2006 Act; or

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- (2) Section 4(1) is amended by section 16 of the Act.
 - (3) Section 83 is amended by paragraph 30 of Schedule 4 to the Act.
 - (4) Section 99 is amended by paragraph 42 of Schedule 4 to the Act.
 - (5) Section 115 is amended by paragraph 54 of Schedule 4 to the Act.
 - (6) Section 126 is amended by sections 213(7) and 220(7) of, and paragraph 63 of Schedule 4 to, the Act.
 - (7) 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.
 - (8) 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.
 - (9) [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.
 - (10) Section 11 of the 2006 Act sets out general functions of CCGs.
 - (11) 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.
 - (12) 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.
 - (13) Paragraph 9 of Schedule 1 to the 2006 Act is amended by section 17(2) and (10)(b) of the Act.
 - (14) *See* section 14Z24(2) of the 2006 Act (interpretation) as regards functions of the Secretary of State that are exercisable by a CCG.
 - (15) 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.
 - (16) Section 2B is inserted into the 2006 Act by section 12 of the Act.
 - (17) Section 6C is inserted into the 2006 Act by section 18(1) of the Act.
 - (18) Section 111 is amended by section 29(1) and (2) of the Act.
 - (19) 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.

- (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)⁽²⁰⁾ 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)⁽²¹⁾ 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⁽²²⁾ (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)—
- (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.

⁽²⁰⁾ Section 223B is inserted into the 2006 Act by section 24 of the Act.

⁽²¹⁾ Section 223G is inserted into the 2006 Act by section 27 of the Act.

⁽²²⁾ 2003 c. 26.