
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 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⁽¹⁾, 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.

⁽¹⁾ See Part 3 of [S.I. 2012/2996](#) for services to be commissioned by the Board.

- (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) 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.