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## STATUTORY INSTRUMENTS

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# 2012 No. 2996

## The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012

### PART 7

#### Standing rules: decisions about drugs and other treatments

#### Interpretation

**33.** In this Part—

“health care intervention” includes the use of a medicine or medical device, diagnostic technique, surgical procedure or other therapeutic intervention;

“NICE” means—

- (a) until the coming into force of section 232 of the 2012 Act <sup>M1</sup>, the National Institute for Health and Clinical Excellence <sup>M2</sup>; and
- (b) from the coming into force of that section, the National Institute for Health and Care Excellence;

“relevant NICE recommendations” means—

- (a) any directions given by the Secretary of State as to the application of sums paid to a Primary Care Trust under section 228 of the 2006 Act (public funding by Primary Care Trusts) in relation to a health care intervention recommended by NICE; and
- (b) from the coming into force of section 237(8) of the 2012 Act (NICE advice, guidance, information and recommendations), recommendations specified, or recommendations of a description specified, in regulations made under that section where the relevant body—
  - (i) is specified in such regulations as required to comply with the recommendation, or
  - (ii) is a health and social care body of a description specified in such regulations as a health and social care body that is required to comply with the recommendation.

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#### Marginal Citations

**M1** Section 232 of the 2012 Act establishes a body corporate to be known as the National Institute for Health and Care Excellence.

**M2** The National Institute for Health and Clinical Excellence is a Special Health Authority established by [S.I. 1999/220](#), as amended by [S.I. 1999/2219](#), [2002/1760](#), [2005/497](#) and [2012/476](#). It is abolished by section 248 of the 2012 Act.

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### **Duty of a relevant body in respect of the funding and commissioning of drugs and other treatments**

**34.**—(1) A relevant body must have in place arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available for persons for whom the relevant body has responsibility.

(2) Arrangements under paragraph (1) must—

- (a) ensure that the relevant body complies with relevant NICE recommendations; and
- (b) include arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention.

### **Duty to give reasons for decisions**

**35.**—(1) A relevant body must—

- (a) publish on its website a written statement of its reasons for any general policy it has on whether a particular healthcare intervention is to be made available for persons for whom it has responsibility; or
- (b) where it has not published such a statement, provide a written statement of the reasons for any such policy when any person makes a written request for such a statement.

(2) Where a relevant body—

- (a) makes a decision to refuse a request for the funding of a health care intervention for a person; and
- (b) its general policy is not to fund that intervention,

the relevant body must provide that person with the reasons for that decision in writing.

### **Duty to provide written information**

**36.** Each relevant body must compile information in writing describing the arrangements it has made pursuant to the requirements in regulation 34 and must ensure that that information is—

- (a) published on the website of the relevant body; and
- (b) available to inspect at the head or main office of the relevant body.

### **[<sup>F1</sup>Transitional provisions**

**37.**—(1) Where—

- (a) before 1st July 2022, a person has made a request for a written statement of the reasons for a clinical commissioning group's general policy on whether a particular health care intervention is to be made available pursuant to regulation 35(1)(b), and
- (b) a written statement of reasons has not been provided before 1st July 2022 by the clinical commissioning group to whom that request was made,

the relevant body with responsibility for that person must provide a written statement of reasons for that general policy as soon as reasonably practicable.

(2) Where a clinical commissioning group—

- (a) before 1st July 2022, has made a decision to refuse a request for the funding of a health care intervention in respect of a person where the clinical commissioning group's general policy is not to fund that intervention, but

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- (b) has not provided that person with a written statement of reasons for that decision pursuant to regulation 35(2),

the relevant body with responsibility for that person must provide a written statement of reasons to that person as soon as reasonably practicable.

- (3) Where a clinical commissioning group—

- (a) before 1st July 2022, has made a decision to fund a health care intervention for a person where the clinical commissioning group’s general policy is not to fund that intervention, but

- (b) has not notified that person of that decision,

the relevant body with responsibility for that person must notify that person as soon as reasonably practicable of that decision, and fund that intervention.

(4) Where, before 1st July 2022, a clinical commissioning group has received a request for the funding of a health care intervention but has not determined it, the relevant body with responsibility for the person who made the request must—

- (a) decide whether or not to fund that intervention, and

- (b) if the decision is to refuse to fund that intervention, provide a written statement of reasons to that person as soon as reasonably practicable.]

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#### **Textual Amendments**

- F1** [Reg. 37](#) substituted (1.7.2022) by [The Health and Care Act 2022 \(Consequential and Related Amendments and Transitional Provisions\) Regulations 2022 \(S.I. 2022/634\)](#), regs. 1(2), **209(7)**

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**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- reg. 39(9) inserted by [S.I. 2024/302 reg. 2\(5\)\(c\)](#)