Draft Regulations laid before Parliament under section 272(6)(zb) of the National Health Service Act 2006, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2017 No. 0000

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service Commissioning Board (Additional Functions) Regulations 2017

Made - - - -	*2017*
Coming into force - -	*1st April 2017*

The Secretary of State, in exercise of the powers conferred by sections 13Z1 and 272(8)(a) of the National Health Service Act 2006(**1**), makes the following Regulations.

In accordance with section 272(6)(zb) of that Act(**2**), a draft of this instrument was laid before and approved by a resolution of each House of Parliament.

Citation and commencement

1. These Regulations may be cited as the National Health Service Commissioning Board (Additional Functions) Regulations 2017 and come into force on 1st April 2017.

Interpretation

2. In these Regulations—

"2006 Act" means the National Health Service Act 2006;

"health service" means the health service continued under section 1(1) of the 2006 Act(**3**); and

"regulation 4(1) function" means the function specified in regulation 4(1).

(**1**) 2006 c.41. Section 13Z1 of the National Health Service Act 2006 ("the 2006 Act") was inserted by section 23(1) of the Health and Social Care Act 2012 (c.7) ("the 2012 Act"). Section 275 of the 2006 Act defines "regulations" as regulations made by the Secretary of State. By virtue of section 271(1) of the 2006 Act, the Secretary of State's power in section 13Z1 of that Act to make these Regulations is exercisable only in relation to England.

(**2**) Section 272(6)(zb) of the 2006 Act was inserted by section 23(2) of the 2012 Act.

(**3**) Section 275(1) of the 2006 Act defines "the health service" as including the health service in Wales. These regulations apply only to the health service in England.

Additional functions of the Board

3. The Board(**4**) is to have the functions specified in regulations 4 to 6.

Power to conclude and manage framework agreements

4.—(1) The Board may conclude and manage framework agreements to facilitate the purchase and supply of a service, drug, medicine or other substance or product to which paragraph (2) applies.

(2) This paragraph applies to a service, drug, medicine or other substance or product that is to be provided as part of the health service for—

(a) the purposes of preventing, diagnosing, monitoring or treating a physical or mental illness;

(b) the purposes of providing care to an individual; or

(c) a purpose related to any matter mentioned in sub-paragraph (a) or (b).

(3) In this regulation—

(a) "framework agreement" means an agreement between the Board and one (or more than one) economic operator (within the meaning of regulation 2 (definitions) of the Public Contracts Regulations 2015(**5**)), the purpose of which is to establish the terms governing contracts to be entered into during a given period, in particular with regard to price and, where appropriate, the quantity envisaged; and

(b) "other substance or product" includes—

(i) medical supplies within the meaning of section 260(5) of the 2006 Act(**6**);

(ii) a medical device within the meaning of regulation 2 (interpretation) of the Medical Devices Regulations 2002(**7**); and

(iii) a human blood component.

Duty to provide assistance

5. In relation to the exercise of the regulation 4(1) function, the Board must comply with a request made by the Secretary of State for any assistance the Secretary of State considers necessary or expedient for the purposes of the functions of the Secretary of State relating to the health service.

Duty to consult and collaborate

6.—(1) For the purposes of exercising the regulation 4(1) function, the Board must consult and collaborate with the registered pharmacist, or a person representing the registered pharmacist, of every trust.

(2) In this regulation—

(a) "the registered pharmacist" means a person falling within the definition of "registered pharmacist" in section 275 (interpretation) of the 2006 Act who has been nominated by a trust for the purposes of paragraph (1); and

(b) "trust" means—

(i) a body in England established by an order made under section 25(1) of the 2006 Act as a National Health Service trust(**8**); or

(**4**) Section 275(1) of the 2006 Act defines "the Board" as the National Health Service Commissioning Board. This definition was inserted by section 55(1) of, and paragraph 138(2) of Schedule 4 to, the 2012 Act. The Board is a body corporate established under section 1H of the 2006 Act and is also known as NHS England. Section 1H was inserted by section 9(1) of the 2012 Act.
(**5**) S.I. 2015/102. Amendments have been made to S.I. 2015/102 but none are relevant to these Regulations.
(**6**) Section 260(5) of the 2006 Act defines "medical supplies" as including surgical, dental and optical materials and equipment.
(**7**) S.I. 2002/618, as amended. Amendments relevant to these Regulations have been made by S.I. 2008/2936.
(**8**) NHS trusts are to be abolished under section 179(1) of the 2012 Act. Section 179(1) is not yet in force.

(ii) a body included in the register referred to in section 39(1) of the 2006 Act(**9**) (register of NHS foundation trusts).

Signed by authority of the Secretary of State for Health.

Name
Parliamentary Under-Secretary of State,
Department of Health

Date

(**9**) Section 39 has been amended by the 2012 Act but the amendments are not relevant to these Regulations.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations are made under section 13Z1 of the National Health Service Act 2006 ("the 2006 Act"). They confer additional functions on the National Health Service Commissioning Board ("the Board") in relation to the National Health Service (NHS) in England. The Board is also known as NHS England.

Regulation 4 confers a new power ("the regulation 4(1) function") on the Board to conclude and manage framework agreements with suppliers and manufacturers of services, drugs, medicines and other substances and products. The services, drugs, medicines, etc. in question are those that are intended to be provided under the NHS for the purposes of preventing, diagnosing, monitoring or treating a physical or mental illness, to provide care to a person or for a purpose related to any of these matters.

The framework agreements will be used mainly by NHS trusts and NHS foundation trusts to enter into contracts with suppliers and manufacturers who are parties to the framework agreements for the purchase of services, drugs, medicines, etc. on the terms and conditions (including price) stipulated in the framework agreements.

Regulation 5 imposes a duty on the Board to provide assistance requested by the Secretary of State for the purposes of the Secretary State's functions relating to the NHS. This duty applies in the context of the regulation 4(1) function, for example, in how the function is to be exercised or in providing assistance that the Board is able to provide as a consequence of exercising the function.

Under regulation 6, for the purposes of exercising the regulation 4(1) function, the Board must consult and collaborate with every NHS trust and NHS foundation trust through a registered pharmacist nominated by each trust (usually the chief pharmacist) or with the representative of any such registered pharmacist. The consultation and collaboration envisaged includes, in particular, considering the drugs, medicines, services, etc. that are to be the subject of framework agreements to be concluded under regulation 4(1).

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sectors is foreseen.