STATUTORY INSTRUMENTS

2013 No. 257

NATIONAL HEALTH SERVICE, ENGLAND PUBLIC PROCUREMENT, ENGLAND

The National Health Service (Procurement, Patient Choice and Competition) Regulations 2013

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

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 75, 76, 77 and 304(9) and (10) of the Health and Social Care Act 2012(1).

PART 1

General

Citation, commencement, interpretation and application

- 1.—(1) These Regulations may be cited as the National Health Service (Procurement, Patient Choice and Competition) Regulations 2013 and come into force on 1st April 2013.
 - (2) In these Regulations—
 - "the 2006 Act" means the National Health Service Act 2006(2);
 - "the 2012 Regulations" means the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012(3);
 - "the Board" means the National Health Service Commissioning Board(4);
 - "CCG" means clinical commissioning group(5);

^{(1) 2012} c. 7.

²⁰⁰⁶ c. 41.

S.I. 2012/2996.

The National Health Service Commissioning Board is established by section 1H of the National Health Service Act 2006 (c. 41) ("the 2006 Act"). Section 1H is inserted by section 9(1) of the Health and Social Care Act 2012 (c. 7) ("the 2012 Act").

A clinical commissioning group is a body established under section 14D of the 2006 Act. Section 14D is inserted by section 25(1) of the 2012 Act. See also section 1I of the 2006 Act, inserted by section 10 of the 2012 Act.

"patient" has the same meaning as in the 2006 Act(6);

"provider" means a person who provides health care services for the purposes of the NHS(7), or is interested in doing so;

"relevant body" means a CCG or the Board.

- (3) References to a "contract" in these Regulations include an NHS contract (which has the same meaning as in section 9 of the 2006 Act).
- (4) These Regulations do not apply in respect of pharmaceutical services, including local pharmaceutical services, under Part 7 of the 2006 Act.

PART 2

Requirements as to procurement, patient choice and competition

Procurement: objective

- **2.** When procuring health care services(8) for the purposes of the NHS (including taking a decision referred to in regulation 7(2)), a relevant body must act with a view to—
 - (a) securing the needs of the people who use the services,
 - (b) improving the quality of the services, and
 - (c) improving efficiency in the provision of the services.

Procurement: general requirements

- **3.**—(1) When procuring health care services for the purposes of the NHS (including taking a decision referred to in regulation 7(2)), a relevant body must comply with paragraphs (2) to (4).
 - (2) The relevant body must—
 - (a) act in a transparent and proportionate way, and
 - (b) treat providers equally and in a non-discriminatory way, including by not treating a provider, or type of provider, more favourably than any other provider, in particular on the basis of ownership.
 - (3) The relevant body must procure the services from one or more providers that—
 - (a) are most capable of delivering the objective referred to in regulation 2 in relation to the services, and
 - (b) provide best value for money in doing so.
- (4) In acting with a view to improving quality and efficiency in the provision of the services the relevant body must consider appropriate means of making such improvements, including through—
 - (a) the services being provided in an integrated way (including with other health care services, health-related services, or social care services).
 - (b) enabling providers to compete to provide the services, and
 - (c) allowing patients a choice of provider of the services.

⁽⁶⁾ See in particular section 275(1) of the 2006 Act.

⁽⁷⁾ See section 64(3) and (4) of the 2012 Act for the meaning of "health care services" and "the NHS".

⁽⁸⁾ Section 75(2) of the 2012 Act provides that requirements imposed by these Regulations apply to an arrangement for the provision of goods and services only if the value of the consideration attributable to the services is greater than that attributable to the goods.

- (5) A relevant body must, in relation to each contract awarded by it for the provision of health care services for the purposes of the NHS, maintain a record of—
 - (a) in the case of a contract awarded by the Board, details of how in awarding the contract it complies with its duties under sections 13D and 13E (duties as to effectiveness, efficiency etc and improvement in quality of services) of the 2006 Act(9);
 - (b) in the case of a contract awarded by a CCG, details of how in awarding the contract it complies with its duties under sections 14Q and 14R of that Act(10) (duties as to effectiveness, efficiency etc and improvement in quality of services).
- (6) In paragraph (4), "health-related services" and "social care services" have the same meaning as in section 62(11) of the Health and Social Care Act 2012.

Advertisements and expressions of interest

- 4.—(1) The Board must maintain and publish details of a website dedicated to—
 - (a) advertising by relevant bodies of opportunities for providers to provide health care services for the purposes of the NHS, and
 - (b) publication of records which must be published under regulation 9(1).
- (2) Where advertising an intention to seek offers from providers in relation to a new contract for the provision of health care services for the purposes of the NHS, a relevant body must publish a contract notice on the website maintained by the Board under paragraph (1).
 - (3) A contract notice must include—
 - (a) a description of the services required to be provided, and
 - (b) the criteria against which any bids for the contract will be evaluated.
- (4) A relevant body must secure that arrangements exist for enabling providers to express an interest in providing any health care service for the purposes of the NHS.
- (5) In this regulation and regulation 5, "contract notice" means a notice inviting offers to provide the services to which the contract to be awarded is to apply.

Award of a new contract without a competition

- **5.**—(1) A relevant body may award a new contract for the provision of health care services for the purposes of the NHS to a single provider without advertising an intention to seek offers from providers in relation to that contract where the relevant body is satisfied that the services to which the contract relates are capable of being provided only by that provider.
- (2) The services are to be determined as capable of being provided by a single provider only when—
 - (a) for technical reasons, or for reasons connected with the protection of exclusive rights, the contract may be awarded only to that provider; or
 - (b) (only if it is strictly necessary) for reasons of extreme urgency brought about by events unforeseeable by, and not attributable to, the relevant body, it is not possible to award the contract to another provider within the time available to the relevant body for securing the provision of the services.
- (3) For the purposes of paragraph (1), a relevant body is not to be treated as having awarded a new contract—

⁽⁹⁾ Sections 13D and 13E are inserted into the 2006 Act by section 23(1) of the 2012 Act.

⁽¹⁰⁾ Sections 14Q and 14R are inserted into the 2006 Act by section 26 of the 2012 Act.

- (a) where the rights and liabilities under a contract have been transferred to the relevant body from the Secretary of State, a Strategic Health Authority or a Primary Care Trust; or
- (b) where there is a change in the terms and conditions of a contract as a result of—
 - (i) a change in the terms and conditions drafted by the Board under regulation 17 of the 2012 Regulations (terms and conditions to be drafted by the Board for inclusion in commissioning contracts), or
 - (ii) new terms and conditions drafted by the Board under that regulation.

Conflicts between interests in purchasing health care services and supplying such services

- **6.**—(1) A relevant body must not award a contract for the provision of health care services for the purposes of the NHS where conflicts, or potential conflicts, between the interests involved in commissioning such services and the interests involved in providing them affect, or appear to affect, the integrity of the award of that contract.
- (2) In relation to each contract that it has entered into for the provision of health care services for the purposes of the NHS, a relevant body must maintain a record of how it managed any conflict that arose between the interests in commissioning the services and the interests involved in providing them
 - (3) An interest referred to in paragraph (1) includes an interest of—
 - (a) a member of the relevant body,
 - (b) a member of its governing body,
 - (c) a member of its committees or sub-committees or committees or sub-committees of its governing body, or
 - (d) an employee.

Qualification of providers

- 7.—(1) For the purpose of taking a decision referred to in paragraph (2), a relevant body must establish and apply transparent, proportionate and non-discriminatory criteria.
 - (2) The decisions are—
 - (a) determining which providers qualify to be included on a list from which a patient is offered a choice of provider in respect of first outpatient appointment with a consultant or a member of a consultant's team.
 - (b) determining which providers qualify to be included on a list from which a patient is otherwise offered a choice of provider,
 - (c) determining which providers to enter into a framework agreement with, and
 - (d) selecting providers to bid for potential future contracts to provide health care services for the purposes of the NHS.
- (3) When taking a decision referred to in paragraph (2)(a), a relevant body may not refuse to include a provider on a list where that provider meets the criteria established by the relevant body for the purposes of that decision.
- (4) When taking a decision referred to in paragraph (2)(b), a relevant body may not refuse to include a provider on a list where that provider meets the criteria established by the relevant body for the purposes of that decision, except where to do so would mean exceeding a limit set by the relevant body on the number of providers to be included on the list.
- (5) When taking a decision referred to in paragraph (2)(c), a relevant body may not refuse to enter into a framework agreement with a provider that meets the criteria established by the relevant

body for the purposes of that decision, except where to do so would mean exceeding a limit set by the relevant body on the number of providers who are to enter into the framework agreement.

- (6) When taking a decision referred to in paragraph (2)(d), a relevant body may not refuse to select a provider that meets the criteria established by the relevant body for the purposes of that decision, except where to do so would mean exceeding a limit set by the relevant body on the number of selected providers.
- (7) In this regulation, a "framework agreement" means an agreement or other arrangement between one or more relevant bodies and one or more providers which establishes the terms under which the provider will enter into one or more contracts, for the provision of health care services for the purposes of the NHS, with a relevant body in the period during which the framework agreement applies.
- (8) This regulation does not apply to the extent that any relevant criteria are laid down by or under any enactment.

Assistance or support for purchasing activities

- **8.**—(1) This paragraph applies where a relevant body has arrangements for a person to assist or support the body in the exercise of its functions, in so far as those functions involve the commissioning of health care services for the purposes of the NHS.
- (2) Where paragraph (1) applies, the relevant body must ensure that the person acts in accordance with the requirements in regulations 2, 3, 4(2) to (4), 5 to 7, 9 and 10, in so far as they apply in relation to an activity performed by that person.

Record of contracts awarded

- **9.**—(1) A relevant body must maintain, and publish on the website maintained by the Board under regulation 4(1), a record of each contract it awards for the provision of health care services for the purposes of the NHS.
 - (2) Such a record must, in particular, include in relation to each contract awarded—
 - (a) the name of the provider and the address of its registered office or principal place of business,
 - (b) a description of the health care services to be provided,
 - (c) the total amount to be paid or, where the total amount is not known, the amounts payable to the provider under the contract,
 - (d) the dates between which the contract provides for the services to be provided, and
 - (e) a description of the process adopted for selecting the provider.

Anti-competitive behaviour

- 10.—(1) When commissioning health care services for the purposes of the NHS, a relevant body must not engage in anti-competitive behaviour(11) which is against the interests of people who use health care services for the purposes of the NHS.
- (2) An arrangement for the provision of health care services for the purposes of the NHS must not include any restrictions on competition that are not necessary for the attainment of intended outcomes which are beneficial for people who use such services.

- (3) Paragraphs (1) and (2) do not apply to behaviour of a relevant body, or a restriction on competition, to the extent to which engagement in such behaviour or such a restriction is necessary to comply with a requirement—
 - (a) imposed by or under any enactment, or
 - (b) imposed by or under the EU Treaties or the EEA agreement and having legal effect in the United Kingdom without further enactment.

Patient choice: primary medical services

- 11.—(1) The Board must not restrict the ability of an individual—
 - (a) to apply for inclusion in the list of patients of the practice of the individual's choice,
 - (b) to express a preference to receive services, from the practice in whose list of patients the individual is included, from a particular performer or class of performer either generally or in relation to any particular condition.
- (2) Paragraph (1) does not apply to the inclusion in a contractor's contract of any term which provides for the contractor to refuse an application for inclusion in its list of patients, or not to agree to any preference expressed to receive services from a particular performer or class of performer, in accordance with—
 - (a) Part 2 of Schedule 6 to the National Health Service (General Medical Services Contracts) Regulations 2004(12) (other contractual terms: patients),
 - (b) Part 2 of Schedule 5 to the National Health Service (Personal Medical Services Agreements) Regulations 2004(13) (other contractual terms: patients), or
 - (c) arrangements for the provision of primary medical services made under section 83(2) of the 2006 Act (primary medical services).
 - (3) In this regulation—

"contract" means, as the case may be—

- (a) an arrangement for the provision of primary medical services made under section 83(2) of the 2006 Act, including any arrangements which are made in reliance on a combination of that provision and any other powers to arrange for the provision of health care services for the purposes of the NHS;
- (b) a general medical services contract made under section 84(1) of the 2006 Act (general medical services contracts); or
- (c) an agreement made in accordance with section 92 of the 2006 Act (arrangements by the Board for the provision of primary medical services);

"contractor" means a person who has entered into a contract with the Board;

"performer" means a medical practitioner included in a list prepared in accordance with regulations made under section 91(1) of the 2006 Act (persons performing primary medical services)(14); and

"practice" means the business operated by a contractor for the purposes of delivering primary medical services under Part 4 of the 2006 Act under a contract for the provision of such services.

⁽¹²⁾ S.I. 2004/291. Relevant amendments were made by S.I. 2007/3491 and 2012/970.

⁽¹³⁾ S.I. 2004/627. Relevant amendments were made by S.I. 2007/3491 and 2012/970.

⁽¹⁴⁾ SeeS.I. 2004/585, as amended by S.I. 2010/412.

Patient choice: choice of alternative provider

12. Where regulation 48 of the 2012 Regulations (duty to offer an alternative provider)(15) applies, a relevant body must offer a person a choice of alternative provider in accordance with regulation 48(4) of those Regulations.

PART 3

Investigations, declarations, directions and undertakings

Powers of Monitor to investigate

- 13.—(1) Monitor may investigate a complaint received by it that a relevant body has failed to comply with a requirement imposed by regulations 2 to 12, or by regulations 39(16), 42 or 43 of the 2012 Regulations (choice of health service provider)(17).
- (2) Monitor may on its own initiative investigate whether a relevant body has failed to comply with a requirement imposed by regulation 10.
- (3) Monitor may not investigate a matter which is raised by a complaint under paragraph (1) where the person making the complaint has brought an action under the Public Contracts Regulations 2006(18) in relation to that matter.
- (4) A relevant body must provide Monitor with such information in its possession as Monitor may specify for the purposes of an investigation carried out by virtue of paragraph (1) or (2).
 - (5) The power of Monitor under paragraph (4) includes—
 - (a) power to require the relevant body to provide an explanation of such information as it provides, and
 - (b) in relation to information kept by means of a computer, power to require the information in legible form.

Declaration of ineffectiveness

- **14.**—(1) Monitor may declare that an arrangement for the provision of health care services for the purposes of the NHS is ineffective(**19**).
 - (2) Monitor may only make a declaration under paragraph (1) where it is satisfied that—
 - (a) in relation to that arrangement, a relevant body has failed to comply with a requirement imposed by regulation 2, 3(1) to (4), 4(2) and (3), 5 to 8 or 10(1), and
 - (b) the failure is sufficiently serious.
- (3) Monitor may declare that a term or condition of an arrangement for the provision of health care services for the purposes of the NHS is ineffective where is it satisfied that—

⁽¹⁵⁾ Regulation 48 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations") applies in the circumstances laid down in regulation 47 of, and is subject to regulation 49 of, the 2012 Regulations.

⁽¹⁶⁾ Regulation 39 of the 2012 Regulations is subject to regulations 40 and 41 of the 2012 Regulations.

⁽¹⁷⁾ Section 76(2) of the 2012 Act provides that Monitor may only investigate a complaint received by it where it is satisfied that the person making the complaint has sufficient interest in the arrangement to which the complaint relates.

⁽¹⁸⁾ S.I. 2006/5, as amended by S.I. 2007/3542, 2008/2256, 2008/2683, 2008/2848, 2009/1307, 2009/2992, 2010/976, 2011/1043, 2011/1848, 2011/2053, 2011/2581 and 2011/3058.

⁽¹⁹⁾ Section 76(5) of the 2012 Act provides that where such a declaration is made the arrangement is void; but that does not affect: (a) the validity of anything done pursuant to the agreement, (b) any right acquired or liability incurred under the arrangement, or (c) any proceedings or remedy in respect of such a right or liability.

- (a) in relation to that term or condition, a relevant body has failed to comply with regulation 10(2), and
- (b) the failure is sufficiently serious.
- (4) On a declaration being made under paragraph (3), the term or condition is void; but that does not affect—
 - (a) the validity of anything done pursuant to the term or condition,
 - (b) any right acquired or liability incurred under the term or condition, or
 - (c) any proceedings or remedy in respect of such a right or liability.

Power to give directions

- 15. Monitor may direct a relevant body—
 - (a) to put in place measures for the purpose of preventing failures to comply with a requirement imposed by regulations 2 to 12, or by regulations 39, 42 or 43 of the 2012 Regulations;
 - (b) to put in place measures for the purpose of mitigating the effect of such failures;
 - (c) to vary or withdraw an invitation to tender for the provision of health care services for the purposes of the NHS to prevent or remedy a failure to comply with a requirement imposed by regulations 2 to 8 and 10;
 - (d) to vary an arrangement for the provision of health care services for the purposes of the NHS made in consequence of putting the provision of services out to tender to remedy a failure to comply with a requirement imposed by regulations 2 to 8;
 - (e) to vary an arrangement for the provision of health care services for the purposes of the NHS to remedy a failure to comply with regulation 10;
 - (f) to otherwise remedy a failure to comply with a requirement referred to in subparagraph (a).

Undertakings

16. Monitor may accept an undertaking from a relevant body to take such action of a kind mentioned in regulation 15(a) to (f)(20) as is specified in the undertaking within such period as is so specified.

Actions brought under the Public Contracts Regulations 2006

17. A person who has brought an action under the Public Contracts Regulations 2006 for loss or damage may not bring an action under section 76(7) of the Health and Social Care Act 2012(21) in respect of the whole or part of the same loss or damage.

⁽²⁰⁾ Section 77(3) to (5) and Schedule 9 of the 2012 Act make further provision in relation to any undertakings accepted by Monitor under these Regulations. In particular, Monitor may not continue with any investigation in relation to the matter in question, or make a declaration of ineffectiveness in relation to the arrangement in question.

⁽²¹⁾ Section 76(7) of the 2012 Act provides that a failure to comply with a requirement imposed by regulations made under section 75 of that Act which causes loss or damage is actionable.

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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 impose requirements on the National Health Service Commissioning Board ("the Board") and clinical commissioning groups ("CCGs") in order to ensure good practice in relation to the procurement of health care services for the purposes of the NHS, to ensure the protection of patients' rights to make choices regarding their NHS treatment and to prevent anti-competitive behaviour by commissioners with regard to such services.

Part 2 of the Regulations imposes requirements on the Board and CCGs (together referred to as "relevant bodies") in relation to procurement, patient choice and anti-competitive behaviour.

Regulation 2 lays down a general objective for relevant bodies when procuring health care services for the purposes of the NHS.

Regulation 3 lays down general requirements which are to apply to the procurement of health care services for the purposes of the NHS. This includes requirements for procurement to be carried out in a transparent and proportionate manner and for providers to be treated equally and in a non-discriminatory way.

Regulations 4 and 5 provide for requirements relating to transparency in the award of contracts for the provision of health care services for the purposes of the NHS. Where a relevant body is advertising an intention to seek offers from providers to provide services it must publish a contract notice on a website to be maintained by the Board (regulation 4(1)). A relevant body need not advertise an intention to seek such offers where it is satisfied that the services are only capable of being provided by a particular provider (regulation 5).

Regulation 6 prohibits the award of a contract by a relevant body for the provision of NHS health care services where conflicts between the interests in commissioning the services and the interests in providing them affect, or appear to affect, the integrity of the award of the contract. Regulation 7 requires a relevant body to establish and apply transparent, proportionate and non-discriminatory criteria for the purposes of taking certain decisions in relation to the provision of health care services for the purposes of the NHS.

Regulation 9 requires relevant bodies to maintain and publish a record of all contracts entered into by them for the provision of health care services for the purposes of the NHS.

Regulation 10 lays down a general prohibition on anti-competitive behaviour by relevant bodies which is against the interests of people who use NHS health care services.

Regulation 11 requires the Board not to restrict the ability of a person to apply for inclusion in the list of patients of a practice providing primary medical services, or to express a preference to receive such services from a particular medical practitioner or class of medical practitioner.

Regulation 12 places a requirement on relevant bodies to offer a choice of alternative provider in accordance with regulation 48(4) of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations"), in the circumstances laid down in regulation 47 of the 2012 Regulations.

Part 3 of the Regulations provides Monitor with powers to investigate and take enforcement action in relation to breaches of the requirements imposed on relevant bodies by these Regulations and regulations 39, 42 and 43 (choice of health service provider) of the 2012 Regulations. These include powers for Monitor to declare arrangements for the provision of health care services for the purposes

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of the NHS to be ineffective (regulation 14), to give directions to a relevant body (regulation 15), and to accept undertakings from a relevant body (regulation 16).

Regulation 17 provides that a person who has brought an action for loss or damages under the Public Contracts Regulations 2006 may not bring an action for the same loss or damage resulting from a breach of these Regulations or of regulation 39, 42 or 43 of the 2012 Regulations.

An impact assessment of the effect these Regulations will have on the costs of the business and the voluntary sector is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS and at http://transparency.dh.gov.uk/category/transparency/ias/.