The National Health Service (Procurement, Patient Choice and Competition) Regulations 2013: made under sections 75 to 77 of the Health and Social Care Act 2012 - Notes on each regulation

Introduction

These notes relate to the Regulations made under sections 75 to 77 of the Health and Social Care Act 2012. They have been prepared by the Department of Health in order to assist the reader of the Regulations and help inform any debate. These notes should be read in conjunction with the Regulations themselves. Where a regulation does not seem to require any explanation or comment, none is given.

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<th>Regulation Number and Paragraph</th>
<th>Text of the regulation</th>
<th>Explanation</th>
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<tr>
<td>1(1)</td>
<td>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.</td>
<td>Paragraph 1 provides for the Regulations to come into force from 1 April 2013.</td>
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</tbody>
</table>
| 1(2), (3) & (4)                  | In these Regulations—
  “the 2006 Act” means the National Health Service Act 2006;
  “the 2012 Regulations” means the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012;
  “the Board” means the National Health Service Commissioning Board;
  “CCG” means clinical commissioning group;
  “patient” has the same meaning as in the 2006 Act;
  “provider” means a person who provides health care services for the purposes of the NHS, or is interested in doing so;
  “relevant body” means a CCG or the Board.

References to a “contract” in these Regulations include an NHS contract (which has the same meaning as in section 9 of the 2006 Act).

These Regulations do not apply in respect of pharmaceutical services, including local pharmaceutical services, are not covered by the Regulations. This is because there are other regulations and processes governing those services. Paragraph 2 and 3 provide definitions and interpretation of the key terms used within the Regulations. |
services, including local pharmaceutical services, under Part 7 of the 2006 Act.

**Procurement: objective**

| 2 | 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 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. |

Regulation 2 sets out the general objective that commissioners (the NHS Commissioning Board (“the Board”) and clinical commissioning groups) must pursue in procuring healthcare services for the purposes of the NHS. This objective is to secure services that meet patients’ healthcare needs and improve quality and efficiency.

To avoid doubt the regulation makes clear that it also applies to decisions that may lead to a future contract award, as referred to in regulation 7, which concern, for example, decisions regarding which providers to enter into framework agreements with where no contract has yet been entered into, or which providers qualify to provide services subject to patient choice.

**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). |

Regulation 3 provides the general requirements that commissioners must comply with whenever they carry out any procurement activity as set out in the following paragraphs.

Paragraph 2 requires commissioners to meet overarching requirements: to act transparently, proportionately and without discrimination. In particular, the regulation prohibits a commissioner from treating one provider more favourably than another on the basis of ownership.

Paragraph 3 provides that the basis on which commissioners must choose a provider to deliver services must be on their capability of meeting the needs of patients and delivering the improvements to quality and efficiency set out in regulation 2 and that deliver best value in doing so.

Paragraph 4 enshrines the principles that it is for commissioners to decide how to improve the quality and efficiency of services, and in doing so they should consider integration, competition and extending patient choice as possible means to attaining those benefits for patients.

Paragraph 5 requires commissioners to keep a record of the rationale for their decision to award a contract for NHS services. In particular it requires commissioners to record
| 3(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. | how the contract award enables them to the improve quality and efficiency of services. |
| 3(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
   (b) 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 duties as to effectiveness, efficiency etc and improvement in quality of services). | |
| 3(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 4 requires the Board to maintain a website that commissioners can use to advertise contracts for NHS services and record the contracts they have awarded. This provides for the continuation of a dedicated NHS procurement portal such as the Supply2Health website established by the previous Government. Paragraph 2 requires that where a commissioner has decided to advertise a contract then a contract notice must be published on the website maintained by the Board. |
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<thead>
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<th>Regulation</th>
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<tbody>
<tr>
<td>4(2)</td>
<td>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).</td>
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</tbody>
</table>
| 4(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(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.                                                                                                                      |
| 4(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.                                                                                                                          |
|             | Paragraph 4 requires commissioners to put in place arrangements to enable providers and potential providers to express their interest in delivering services to the commissioner.                                                                                                             |

### Award of a new contract without a competition

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<tr>
<td>5(1)</td>
<td>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.</td>
</tr>
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</table>
| 5(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 |
|             | Regulation 5 allows commissioners to award contracts without an advertisement where they are satisfied that there is only one provider capable of providing those services. It continues the approach under the existing procurement guidance to commissioners and is consistent with UK procurement law. |
|             | Paragraph 2 specifies that the grounds on which there may be considered to be only one capable provider are: for ‘technical reasons’ – i.e. that there is only one provider that can meet the commissioners’ requirements, or, in cases of extreme urgency, outside the control of the commissioner, where it is not possible to award a contract to another provider in the time available. This is consistent with the established provisions of UK procurement law. |
|             | Paragraph 3 has been included to help deliver a smooth transition between commissioning arrangements by providing that contracts transferred from Strategic Health Authorities and Primary Care Trusts to the NHS Commissioning Board or |
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.

For the purposes of paragraph (1), a relevant body is not to be treated as having awarded a new contract—

(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

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.

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.

Regulation 6 requires commissioners to manage conflicts and potential conflicts of interests when awarding a contract by prohibiting the award of a contract where the integrity of the award has been or appears to have been affected by a conflict. It is consistent with the requirements on clinical commissioning groups to manage conflicts of interest set out in the National Health Service Act 2006.

Paragraph 2 requires commissioners to keep appropriate records of how they have managed any conflicts in individual cases and paragraph 3 sets out relevant members and employees who may have an interest.
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

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.

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.

Regulation 7 provides that commissioners must act transparently and fairly when qualifying providers (e.g. to offer services subject to patient choice), appointing providers to frameworks and selecting providers to bid for potential future contracts.

Paragraph 3 prohibits a commissioner from unreasonably refusing to qualify a provider, in respect of a first outpatient appointment with a consultant or a consultant-led team, that meets the criteria the commissioner has set.

Paragraphs 4, 5 and 6 prohibit a commissioner from refusing to otherwise qualify a provider, appoint a provider to a framework, or select them to bid for future contracts, except where to do so would exceed a limit the commissioner has set on the number of providers (e.g. to ensure best value in the provision of the services). It should be noted that in setting any such limit the commissioner would need to meet the requirements to act transparently, proportionately and without discrimination.
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<tr>
<td>7(5)</td>
<td>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.</td>
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<tr>
<td>7(6)</td>
<td>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.</td>
</tr>
<tr>
<td>7(7)</td>
<td>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.</td>
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<tr>
<td>7(8)</td>
<td>This regulation does not apply to the extent that any relevant criteria are laid down by or under any enactment.</td>
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**Assistance or support for purchasing activities**

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<tr>
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<tbody>
<tr>
<td>8(1)</td>
<td>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.</td>
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</table>

Regulation 8 provides that where any third parties, such as another clinical commissioning group or a commissioning support unit, assist or support a commissioner in their procurement activity, the commissioner must ensure that they follow the requirements of the Regulations in the same way the commissioner must do itself.

Guidance has already been issued to commissioners on identifying which commissioner is responsible for expenditure associated with individual patients. This can be found at:
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<tr>
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<tr>
<td>8(2)</td>
<td>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.</td>
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**Record of contract awarded**

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<tr>
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<tbody>
<tr>
<td>9(1)</td>
<td>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.</td>
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</table>
| 9(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. |

Regulation 9 requires commissioners to publish on the website maintained by the Board details of the contracts they have entered into with providers of health care services. Paragraph 2 sets out the particular information that is required to be recorded to help ensure transparency and accountability in relation to a commissioner’s decisions.

**Anti-competitive behaviour**

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<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>10(1)</td>
<td>When commissioning health care services for the purposes of the NHS, a relevant body must not engage in anti-competitive behaviour which is against the interests of people who use health care services for the purposes of the NHS.</td>
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</table>

Regulation 10 establishes a principle that commissioners must not prevent, restrict or distort competition against the interests of patients. This continues the approach as established by the previous administration under the Principles and Rules for Cooperation and Competition. Paragraph 2 clarifies that any arrangement must not include any restrictions which are not necessary to the attainment of over-riding benefits.
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.

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**

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.

Regulation 11 prohibits the Board from restricting the rights to exercise choice that patients have under the NHS Constitution and its handbook, in relation to primary medical services. The Board in turn will hold primary medical services contractors to account to meet their contractual obligations in relation to patient choice.

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(other contractual terms: patients),

(b) Part 2 of Schedule 5 to the National Health Service (Personal Medical Services Agreements) Regulations
2004 (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).

11(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 (primary medical services), 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; 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.

Patient Choice: choice of alternative provider

12 Where regulation 48 of the 2012 Regulations (duty to offer an alternative provider) applies, a relevant body must offer a person a choice of alternative provider in accordance with regulation 48(4) of those Regulations. Regulation 48 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (“the 2012 Regulations”) imposes a duty to offer an alternative provider of health care services in particular circumstances where a person is not going to receive appropriate treatment within an eighteen week period. Inclusion of this requirement in the Regulations will enable Monitor to protect this right to patient choice.
## Powers of Monitor to investigate

<table>
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<tr>
<th>13(1)</th>
<th>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, 42 or 43 of the 2012 Regulations (choice of health service provider).</th>
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<td>13(2)</td>
<td>Monitor may on its own initiative investigate whether a relevant body has failed to comply with a requirement imposed by regulation 10.</td>
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<tr>
<td>13(3)</td>
<td>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 in relation to that matter.</td>
</tr>
<tr>
<td>13(4)</td>
<td>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).</td>
</tr>
</tbody>
</table>
| 13(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.                                                                 |
14(1) Monitor may declare that an arrangement for the provision of health care services for the purposes of the NHS is ineffective.

14(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.

14(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—
(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.

14(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;

Regulation 14(1) and (2) provide for Monitor to set aside an arrangement, including a contract, held by a commissioner where there is a sufficiently serious failure to comply with certain of the requirements in the Regulations.

Paragraph 3 provides for Monitor to set aside a term or condition of an arrangement where there is a sufficiently serious breach of regulation 10(2), i.e. the arrangement contains a restriction on competition which is not necessary for the attainment of over-riding benefits for patients.

Paragraph 4 provides that where a term or condition of an arrangement has been set aside it will be void (i.e. not have effect), but that this will not affect the validity of anything already done under that term or condition.

Regulation 15 gives Monitor powers to direct commissioners to address breaches of the requirements of the Regulations. The regulation also provides for Monitor to direct a commissioner to take actions to prevent or mitigate the effects of such a breach.

In particular, Monitor will be able to direct a commissioner to withdraw or vary an invitation to tender where the commissioner has not complied with the requirements of
(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 sub-paragraph (a).

the Regulations or to prevent a breach. Monitor will also be able to direct a commissioner to vary a contract in order to remedy a breach of the Regulations. This regulation does not give Monitor a power to direct commissioners to tender services.

### Undertakings

<table>
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<tr>
<th>16</th>
<th>Monitor may accept an undertaking from a relevant body to take such action of a kind mentioned in regulation 15(a) to (f) as is specified in the undertaking within such period as is so specified.</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Regulation 16 provides for a commissioner to give Monitor an undertaking that it will take agreed steps to prevent or address a failure to comply with the Regulations (of the kind set out in regulation 15) in lieu of Monitor taking enforcement action.</td>
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</table>

### Actions brought under the Public Contracts Regulations 2006

<table>
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<tr>
<th>17</th>
<th>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 in respect of the whole or part of the same loss or damage.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regulation 17 prevents a person from applying to a court to award compensation for loss or damages for a breach of the Regulations where they have already brought an action for the same (or part of the same) loss or damage under the Public Contract Regulations 2006.</td>
</tr>
</tbody>
</table>