

## SCHEDULE 3

### OTHER CONTRACTUAL TERMS

#### PART 5

#### RECORDS, INFORMATION, NOTIFICATIONS AND RIGHTS OF ENTRY

##### Patient records

**33.**—(1) The contractor shall ensure that a full, accurate and contemporaneous record is kept in the patient record in respect of the care and treatment given to each patient under the agreement, including treatment given to a patient who is referred to the contractor.

(2) The patient record may be kept in electronic form.

(3) The patient record shall include details of any private services (to the extent that it is provided with services under the agreement) and shall be kept with—

- (a) a copy of any treatment plan or referral treatment plan given to the patient pursuant to paragraph 2 of Schedule 1 (referral services) or paragraph 8 of this Schedule;
- (b) all radiographs, photographs and study casts taken or obtained by it as part of the services provided to that patient;
- (c) where an orthodontic course of treatment has been provided to a patient, a copy of the orthodontic treatment plan;
- (d) where information is to be submitted to [F<sup>1</sup>NHS England]F<sup>2</sup>... in accordance with paragraph 39 and that information is submitted or collated electronically—
  - (i) the written declaration form in respect of exemption under paragraph 1(1) of Schedule 12ZA to the Act duly made and completed in accordance with regulations made under section 79 of, and paragraph 7(a) to Schedule 12ZA to, that Act; and
  - (ii) a note of the evidence in support of that declaration; and
- (e) the statement concerning any custom-made devices provided by any person as a consequence of regulation 15 of the Medical Devices Regulations 2002<sup>M1</sup> (procedures for custom-made devices) in respect of services being provided to that patient.

(4) The patient record and the items referred to in sub-paragraph (3) shall be retained for a period of two years beginning with—

- (a) the date on which—
  - (i) a course of treatment or orthodontic course of treatment is terminated; or
  - (ii) a course of treatment or an orthodontic course of treatment is completed; or
- (b) in respect of courses of treatment or orthodontic courses of treatment not falling within paragraph (a)(i) or (a)(ii) the date by which no more services can be provided as part of that course of treatment or orthodontic course of treatment by virtue of paragraph 5(4)(b) of Schedule 1 or paragraph 7(4)(b) of this Schedule.

(5) Nothing in this paragraph shall affect any property right which the contractor may have in relation to the records, radiographs, photographs and study models referred to in this paragraph.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F2** Words in Sch. 3 para. 33(3)(d) omitted (1.4.2013) by virtue of [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(16)(b)** (with Sch. 2)

#### Marginal Citations

- M1** [S.I. 2002/618](#).

### Confidentiality of personal data

**34.** The contractor shall nominate a person with responsibility for practices and procedures relating to the confidentiality of personal data held by it.

### Patient information

**35.—(1)** The contractor shall ensure that there is displayed in a prominent position in its practice premises, in a part to which patients have access—

- (a) in respect of its practice based quality assurance system referred to in paragraph 78, a written statement relating to its commitment to the matters referred to in paragraph 78(4);
- [<sup>F3</sup>(b) such information relating to NHS Charges as is supplied by [<sup>F1</sup>NHS England] for the purposes of providing information to patients; and]
- (c) information about the complaints procedure which it operates in accordance with Part 6, giving the name and title of the person nominated by the contractor in accordance with paragraph 50(2)(a).

(2) The contractor shall—

- (a) compile a document (in this paragraph called a “patient information leaflet”) which shall include the information specified in Schedule 4;
- (b) review its patient information leaflet at least once in every period of 12 months and make any amendments necessary to maintain its accuracy; and
- (c) make available a copy of the leaflet, and any subsequent updates, to its patients and prospective patients.

(3) The requirements in sub-paragraph (2) do not apply to any contractor to the extent that it provides services to persons detained in prison.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F3** Sch. 3 para. 35(1)(b) substituted (1.4.2013) by [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(17)** (with Sch. 2)

**[<sup>F4</sup>Information about the contractor’s practice**

**35A.**—(1) The contractor must ensure that a comprehensive and accurate profile in respect of its practice is provided to NHS England for the purpose of display on the NHS.uk website.

(2) The contractor must review the information contained in the profile referred to in paragraph (1) at least once in every period of 90 days from the date the profile is provided in accordance with paragraph (1).

(3) If, on such a review, it appears to the contractor that any of that information is inaccurate or incomplete, the contractor must provide NHS England with an updated profile in respect of its practice.]

**Textual Amendments**

**F4** Sch. 3 para. 35A inserted (25.11.2022) by [The National Health Service \(Primary Dental Services\) \(Amendment\) Regulations 2022 \(S.I. 2022/1132\)](#), regs. 1(1), **5**

**Provision of and access to information: [<sup>F1</sup>NHS England]**

**36.**—(1) The contractor shall, at the request of [<sup>F1</sup>NHS England]—

- (a) produce to [<sup>F1</sup>NHS England] or to a person authorised in writing by [<sup>F1</sup>NHS England] in such format, and at such intervals or within such time, as [<sup>F1</sup>NHS England] specifies; or
- (b) allow [<sup>F1</sup>NHS England], or a person authorised in writing by it to access,

the information specified in sub-paragraph (2).

(2) The information specified for the purposes of sub-paragraph (1) is—

- (a) any information which is reasonably required by [<sup>F1</sup>NHS England] for the purposes of or in connection with the agreement; and
- (b) any other information which is reasonably required in connection with [<sup>F1</sup>NHS England’s] functions,

and includes the contractor's patient records.

**Textual Amendments**

**F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

**Requests for information from Patients' Forums**

**<sup>F5</sup>37.** . . . . .

**Textual Amendments**

**F5** Sch. 3 para. 37 omitted (1.4.2008) by virtue of [The Local Involvement Networks Regulations 2008 \(S.I. 2008/528\)](#), reg. 1(2), **Sch. para. 10(1)(a)**

**Inquiries about prescriptions and referrals**

**38.**—(1) A contractor shall, subject to sub-paragraphs (2) and (3), sufficiently answer any inquiries whether oral or in writing from [F1NHS England] concerning—

- (a) any prescription form issued by a prescriber;
- (b) the considerations by reference to which prescribers issue such forms;
- (c) the referral by or on behalf of the contractor of any patient for any other services provided under the Act; or
- (d) the considerations by which the contractor makes such referrals or provides for them to be made on its behalf.

(2) An inquiry referred to in sub-paragraph (1) may only be made for the purpose either of obtaining information to assist [F1NHS England] to discharge its functions or of assisting the contractor in the discharge of its obligations under the agreement.

(3) The contractor shall not be obliged to answer any inquiry referred to in sub-paragraph (1) unless it is made—

- (a) in the case of sub-paragraph (1)(a) or (1)(b), by an appropriately qualified health care professional; or
- (b) in the case of sub-paragraph (1)(c) or (1)(d), by an appropriately qualified dental practitioner,

appointed in either case by [F1NHS England] to assist it in the exercise of its functions under this paragraph and the person produces, on request, written evidence that he is authorised by [F1NHS England] to make such inquiry on its behalf.

**Textual Amendments**

**F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

**Notification of a course of treatment, orthodontic course of treatment etc.**

**39.**—(1) Subject to paragraph (2), the contractor shall, within two months of the date upon which—

- (a) it completes a course of treatment in respect of mandatory or additional services;
- (b) it completes a case assessment in respect of an orthodontic course of treatment that does not lead to a course of treatment;
- (c) it provides an orthodontic appliance following a case assessment in respect of orthodontic treatment;
- (d) it completes a course of treatment in respect of orthodontic treatment;
- (e) it completes a course of treatment in respect of mandatory services or additional services or orthodontic course of treatment is terminated; or
- (f) in respect of courses not falling with sub-paragraph (d) or (e), no more services can be provided by virtue of paragraph 5(4)(b) of Schedule 1 (orthodontic course of treatment) or paragraph 7(4)(b) of this Schedule,

[F6subject to sub-paragraph (5), send to [F1NHS England] by means of electronic submission], the information specified in paragraph (3).

F7(2) .....

- (3) The information referred to in sub-paragraphs (1) and (2) comprise of —
- (a) details of the patient to whom it provides services;
  - (b) details of the services provided (including any appliances provided) to that patient;
  - (c) details of any NHS Charge payable and paid by that patient; and
  - <sup>F8</sup>(d) in the case of a patient who is exempt from NHS Charges, the information required under sub-paragraph (4).]
- <sup>F9</sup>(4) In the case of a patient who is exempt from NHS Charges, the contractor must provide <sup>F1</sup>NHS England] (or a person authorised on <sup>F1</sup>NHS England's] behalf) with—
- (a) such details of that exemption as <sup>F1</sup>NHS England] may reasonably request; and
  - (b) the written declaration.
- (5) <sup>F1</sup>NHS England] may accept submission of the information mentioned in sub-paragraph (2) in paper form in such exceptional circumstances as <sup>F1</sup>NHS England] may reasonably determine.
- (6) In this regulation, ‘electronic submission’ means the submission of information electronically via a computer system approved by <sup>F1</sup>NHS England].]

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F6** Words in Sch. 3 para. 39(1) substituted (1.5.2019) by virtue of [The National Health Service \(Primary Dental Services and General Ophthalmic Services\) \(Amendment\) Regulations 2017 \(S.I. 2017/1056\)](#), regs. 1(3), **4(3)(a)** (with reg. 5)
- F7** Sch. 3 para. 39(2) omitted (1.4.2013) by virtue of [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(20)(b)** (with Sch. 2)
- F8** Sch. 3 para. 39(3)(d) substituted (1.5.2019) by [The National Health Service \(Primary Dental Services and General Ophthalmic Services\) \(Amendment\) Regulations 2017 \(S.I. 2017/1056\)](#), regs. 1(3), **4(3)(b)** (with reg. 5)
- F9** Sch. 3 para. 39(4)-(6) inserted (1.5.2019) by [The National Health Service \(Primary Dental Services and General Ophthalmic Services\) \(Amendment\) Regulations 2017 \(S.I. 2017/1056\)](#), regs. 1(3), **4(3)(c)** (with reg. 5)

#### Annual report and review

**40.**—(1) <sup>F1</sup>NHS England] shall provide to the contractor an annual report relating to the agreement which shall contain the same categories of information for all persons who hold agreements with <sup>F1</sup>NHS England].

(2) Once <sup>F1</sup>NHS England] has provided the report referred to in sub-paragraph (1), <sup>F1</sup>NHS England] shall arrange with the contractor an annual review of its performance in relation to the agreement.

(3) <sup>F1</sup>NHS England] shall prepare a draft record of the review referred to in sub-paragraph (2) for comment by the contractor and, having regard to such comments, shall produce a final written record of the review.

(4) A copy of the final record referred to in sub-paragraph (3) shall be sent to the contractor.

### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

### Notifications to [F1NHS England]

**41.**—(1) In addition to any requirements of notification elsewhere in these Regulations, the contractor shall notify [F1NHS England] in writing, as soon as reasonably practicable, of—

- (a) any serious incident that, in the reasonable opinion of the contractor, affects or is likely to affect the contractor's performance of its obligations under the agreement; or
- (b) any circumstances which give rise to [F1NHS England's] right to terminate the agreement under paragraph 68 or 69(1).

(2) The contractor shall, unless it is impracticable for it to do so, notify [F1NHS England] in writing within 28 days of any occurrence requiring a change in the information about it published by [F1NHS England] in accordance with regulations made under section 16CA(3) of the Act<sup>M2</sup> (primary dental services).

(3) The contractor shall give notice in writing to [F1NHS England] when a dental practitioner who is performing or will perform services under the agreement—

- (a) leaves the contractor, and the date upon which he left; or
- (b) is employed or engaged by the contractor,

which shall include the name of the dental practitioner who has left, or who has been employed or engaged, together with his professional registration number.

### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**

### Marginal Citations

- M2** Section 16CA was inserted into the Act by section 170 of the 2003 Act.

### [F10] Notice provisions specific to an agreement with a dental corporation

**42.** Where a dental corporation is a party to the agreement, it shall give notice in writing to [F1NHS England] forthwith when—

- (a) it passes a resolution or a court of competent jurisdiction makes an order that the contractor be wound up;
- (b) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the contractor;
- (c) circumstances arise which would enable the court to make a winding up order in respect of the contractor; or
- (d) the contractor is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts).]

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F10** Sch. 3 para. 42 substituted (1.4.2013) by [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(23)** (with Sch. 2)

#### [<sup>F11</sup>Notice provisions specific to an agreement with a company limited by shares

**42A.**—(1) Where a company limited by shares is a party to the agreement, it shall give notice in writing to [<sup>F1</sup>NHS England] forthwith when—

- (a) it passes a resolution or a court of competent jurisdiction makes an order that the contractor be wound up;
  - (b) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the contractor;
  - (c) circumstances arise which would enable the court to make a winding up order in respect of the contractor;
  - (d) the contractor is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts); or
  - (e) changes take place in relation to the ownership of shares in the company.
- (2) A notice under sub-paragraph (e) must—
- (a) provide the name of any person ceasing to own a share in the company;
  - (b) provide the name of any new person acquiring a share in the company; and
  - (c) confirm that following any changes in share ownership, that the company continues to meet the conditions in section 108(1A) of the 2006 Act.

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F11** Sch. 3 paras. 42A, 42B inserted (1.4.2013) by [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(24)** (with Sch. 2)

#### Notice provisions specific to an agreement with a limited liability partnership

**42B.**—(1) Where a limited liability partnership is a party to an agreement it shall give notice to [<sup>F1</sup>NHS England] forthwith when—

- (a) it passes a resolution or a court of competent jurisdiction makes an order that the contractor be wound up;
- (b) circumstances arise which might entitle a creditor or a court to appoint a receiver, administrator or administrative receiver for the contractor;
- (c) circumstances arise which would enable the court to make a winding up order in respect of the contractor;

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Personal Dental Services Agreements) Regulations 2005, PART 5. (See end of Document for details)

- (d) the contractor is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 (definition of inability to pay debts); or
  - (e) any membership changes are notified in accordance with section 9 of the Limited Liability Partnership Act 2000 (registration of membership changes) to the registrar (within the meaning of that Act) in relation to a person who becomes or ceases to be a member or designated member (within the meaning of that Act) and the notice must specify the date on which that person becomes or ceases to be a member or designated member (as the case may be).
- (2) A notice under sub-paragraph (e) must confirm—
- (a) that any new member joining the partnership meets the conditions imposed by regulation 4 (general conditions relating to all agreements); and
  - (b) following the membership changes, that sub-sections 108(1B) or 108(1C) of the 2006 Act continue to apply to the partnership.]

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F11** Sch. 3 paras. 42A, 42B inserted (1.4.2013) by [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(24)** (with Sch. 2)

#### Notifications to patients following a variation of the agreement

**43.** Where the agreement is varied in accordance with Part 9 of this Schedule and, as a result of that variation there is to be a change in the range of services provided by the contractor, the contractor shall ensure that there is displayed in a prominent position in its practice premises, in a part to which patients have access, written details of that change.

#### [<sup>F12</sup>Notification provisions specific to prototype agreements

**43A.** [<sup>F13</sup>Where the contractor has elected to enter into a prototype agreement, except for CDS prototype contractors, the contractor shall]—

- (a) send to [<sup>F1</sup>NHS England] details of any private treatment provided to a capitated patient attending the practice, in electronic form, whether or not this treatment is associated with services that are provided under the prototype agreement; and
- (b) provide to all patients attending for treatment at its practice a privacy notice in a form approved by [<sup>F1</sup>NHS England] notifying them about the obligation referred to in sub-paragraph (a).]

#### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F12** Sch. 3 para. 43A inserted (1.11.2015) by [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments\) \(No. 2\) Regulations 2015 \(S.I. 2015/1728\)](#), regs. 1(1), **17**
- F13** Words in Sch. 3 para. 43A substituted (1.4.2016) by [The National Health Service \(Primary Dental Services Miscellaneous Amendments and Directions to the NHS Business Services Authority\) Regulations 2016 \(S.I. 2016/298\)](#), regs. 1(1), **25**



## Entry and inspection by [<sup>F1</sup>NHS England]

44.—(1) Subject to—

- (a) the conditions in sub-paragraph (2); and
- (b) sub-paragraph (3),

the contractor shall allow persons authorised in writing by [<sup>F1</sup>NHS England] to enter and inspect the practice premises at any reasonable time.

(2) The conditions referred to in sub-paragraph (1)(a) are that—

- (a) reasonable notice of the intended entry has been given;
- (b) written evidence of the authority of the person seeking entry is produced to the contractor on request; and
- (c) entry is not made to any premises or part of the premises used as residential accommodation without the consent of the resident.

(3) Where the contractor is providing services under the agreement in a prison, the contractor shall not be obliged to comply with sub-paragraph (1), or paragraph <sup>F14</sup>... 46, if—

- (a) the contractor has used its best endeavours to allow [<sup>F1</sup>NHS England]<sup>F15</sup>... or the [<sup>F16</sup>Care Quality Commission] to enter and inspect the practice premises; but
- (b) entry and inspection has been prevented by the prison authorities despite the contractor's best endeavours.

(4) In this paragraph “practice premises” includes a mobile surgery.

### Textual Amendments

- F1** Words in Regulations substituted (6.11.2023) by [The Health and Care Act 2022 \(Further Consequential Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/1071\)](#), reg. 1(1), **Sch. para. 1**
- F14** Words in Sch. 3 para. 44(3) omitted (1.4.2008) by virtue of [The Local Involvement Networks Regulations 2008 \(S.I. 2008/528\)](#), reg. 1(2), **Sch. para. 10(1)(b)(i)**
- F15** Words in Sch. 3 para. 44(3)(a) omitted (1.4.2008) by virtue of [The Local Involvement Networks Regulations 2008 \(S.I. 2008/528\)](#), reg. 1(2), **Sch. para. 10(1)(b)(ii)**
- F16** Words in Sch. 3 para. 44(3)(a) substituted (1.4.2009) by [The Health and Social Care Act 2008 \(Commencement No.9, Consequential Amendments and Transitory, Transitional and Saving Provisions\) Order 2009 \(S.I. 2009/462\)](#), art. 1(1)(b), **Sch. 5 para. 18(a)**

## Entry and inspection by members of Patients' Forums

<sup>F17</sup>45. ....

### Textual Amendments

- F17** Sch. 3 para. 45 omitted (1.4.2008) by virtue of [The Local Involvement Networks Regulations 2008 \(S.I. 2008/528\)](#), reg. 1(2), **Sch. para. 10(1)(c)**

## [<sup>F18</sup>Entry and inspection by the Care Quality Commission

[<sup>F19</sup>46. Subject to paragraph 44(3), the contractor shall allow persons authorised by the Care Quality Commission to enter and inspect the premises in accordance with section 62 of the Health and Social Care Act 2008 (entry and inspection).]]

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Personal Dental Services Agreements) Regulations 2005, PART 5. (See end of Document for details)

---

**Textual Amendments**

- F18** Sch. 3 para. 46 substituted (1.4.2009) by [The Health and Social Care Act 2008 \(Commencement No.9, Consequential Amendments and Transitory, Transitional and Saving Provisions\) Order 2009 \(S.I. 2009/462\)](#), art. 1(1)(b), **Sch. 5 para. 18(b)**
- F19** Sch. 3 para. 46 substituted (1.10.2010) by [The Health and Social Care Act 2008 \(Miscellaneous Consequential Amendments\) Order 2010 \(S.I. 2010/1881\)](#), arts. 1(1), **19**

**[<sup>F20</sup>Entry and viewing by Local Healthwatch organisations**

**46A.** The contractor must comply with the requirement to allow an authorised representative to enter and view premises and observe the carrying-on of activities on those premises in accordance with regulations made under section 225 (duties of services-providers to allow entry by Local Healthwatch organisations or contractors) of the Local Government and Public Involvement Health Act 2007.]

---

**Textual Amendments**

- F20** Sch. 3 para. 46A substituted (1.4.2013) by [The National Health Service \(Primary Dental Services\) \(Miscellaneous Amendments and Transitional Provisions\) Regulations 2013 \(S.I. 2013/364\)](#), regs. 1(1), **39(26)** (with Sch. 2)

**Changes to legislation:**

There are currently no known outstanding effects for the The National Health Service (Personal Dental Services Agreements) Regulations 2005, PART 5.