

## SCHEDULE 3

Regulation 20

### OTHER CONTRACTUAL TERMS

#### PART 1

#### PATIENTS

##### **Persons to whom mandatory services or additional services are to be provided**

**1.**—(1) Subject to sub-paragraphs (3) and (5), the contractor may agree to provide mandatory or additional services under the agreement to any person if a request is made for such services by—

- (a) the person who requires the services; or
- (b) a person specified in sub-paragraph (2), on behalf of the person who requires those services.

(2) For the purposes of sub-paragraph (1)(b), a request for services may be made—

- (a) on behalf of any child by—
  - (i) either parent;
  - (ii) a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989<sup>(1)</sup>; or
  - (iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act; or
- (b) on behalf of any adult who is incapable of making such an application, or authorising such an application to be made on their behalf, by a relative or the primary carer of that person.

(3) The contractor may refuse to provide mandatory or additional services in relation to a person falling outside a specified group of persons only where the contract provides for the contractor to provide such services to a specified group.

(4) The contractor shall only refuse to provide services under the agreement to a person if it has reasonable grounds for doing so which do not relate to—

- (a) a person's race, gender, social class, age, religion, sexual orientation, appearance, disability or medical or dental condition; or
- (b) a person's decision or intended decision to accept private services in respect of himself or a family member.

(5) Sub-paragraph (1) does not apply—

- (a) where the contractor is providing mandatory or additional services in a prison; or
- (b) in any event to dental public health services.

##### **Patient preference of practitioner**

**2.**—(1) Where the contractor has agreed to provide services to a patient, it shall—

- (a) notify the patient (or, in the case of a child or incapable adult, the person who made the application on their behalf) of the patient's right to express a preference to receive services from a particular performer; and
- (b) record in writing any such preference expressed by or on behalf of the patient.

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(1) 1989 c. 41.

(2) The contractor shall endeavour to comply with any reasonable preference expressed under sub-paragraph (1) but need not do so if the preferred performer—

- (a) has reasonable grounds for refusing to provide services to the patient; or
- (b) does not routinely perform the services required by the patient within the practice.

(3) This paragraph does not apply—

- (a) where the contractor is providing mandatory or additional services in a prison; or
- (b) in any event to dental public health services.

### **Violent patients**

3.—(1) Where—

- (a) a patient of the contractor has committed an act of violence or behaved in such a way against any persons specified in sub-paragraph (2) as a consequence of which that person has feared for his safety; and
- (b) the contractor has reported the incident to the police,

the contractor may notify the Relevant Body that it will no longer provide services to that patient under the agreement.

(2) The persons referred to in sub-paragraph (1) are—

- (a) any party to the agreement who is an individual;
- (b) any member of the contractor's staff;
- (c) a person engaged by the contractor to perform or assist in the performance of services under the agreement; or
- (d) any other person present—
  - (i) on the practice premises; or
  - (ii) in the place where services were provided to the patient under the agreement.

(3) Notification under sub-paragraph (1) may be given by any means including telephone, fax or email but if not given in writing shall subsequently be confirmed in writing within seven days (and for this purpose a faxed or email notification is not a written one).

(4) The time at which the contractor notifies the Relevant Body shall be the time at which it makes the telephone call or sends or delivers the notification to the Relevant Body.

(5) The Relevant Body shall—

- (a) acknowledge in writing receipt of the notice from the contractor under sub-paragraph (1); and
- (b) take all reasonable steps to inform the patient concerned as soon as is reasonably practicable.

### **Patients who refuse to pay NHS charges prior to the commencement of, or during, treatment**

4. The contractor may—

- (a) refuse to begin a course of treatment; or
- (b) terminate a course of treatment prior to its completion,

if the contractor has, in accordance with the NHS Charges Regulations, requested that the patient pay a charge in respect of that course of treatment or orthodontic course of treatment, and that patient has failed to pay that charge.

### **Irrevocable breakdown in relationship between contractor and patient**

**5. Where—**

- (a) in the reasonable opinion of the contractor, there has been an irrevocable breakdown in the relationship between the patient and that contractor; and
- (b) notice of such a breakdown has been given to the patient by the contractor,

the contractor may notify the Relevant Body that it will no longer provide services to that patient under the agreement.

## **PART 2**

### **PROVISION OF SERVICES**

#### **Mandatory services**

**6.** Where the agreement provides for a contractor to provide mandatory services, the contractor must provide—

- (a) urgent treatment, at such times as are agreed with the Relevant Body and specified in the agreement; and
- (b) all other mandatory services during normal surgery hours.

#### **Course of treatment**

**7.—(1)** Except in the case of orthodontic services and dental public health services, the contractor shall provide mandatory and additional services to a patient by providing to that patient a course of treatment.

(2) The contractor shall use its best endeavours to ensure that a course of treatment is completed, and that it is so completed within a reasonable time from the date on which—

- (a) the treatment plan was written in accordance with paragraph 8(1); or
- (b) where a treatment plan is not required pursuant to that paragraph, the initial examination and assessment of the patient took place.

(3) Where a contractor provides urgent treatment to a patient, the urgent treatment provided shall constitute a single course of treatment and no other services shall be provided during that course of treatment.

(4) If a course of treatment is—

- (a) terminated before it has been completed; or
- (b) otherwise not completed within a reasonable time,

any further services to be provided to that patient under the agreement must be provided as a new course of treatment.

(5) A course of treatment may only be terminated by—

- (a) the contractor—
  - (i) when the circumstances referred to in paragraph 3(1) of this Schedule (violent patient) occur and notice that it will no longer provide services has been given to the Relevant Body;
  - (ii) where the patient has refused to pay a charge in the circumstances referred to in paragraph 4 of this Schedule (refusal to pay NHS Charges during treatment); or

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- (iii) where, in the reasonable opinion of the contractor, there has been an irrevocable breakdown in the relationship between the patient and the contractor and notice of such a breakdown has been given to the patient and the Relevant Body;
  - (b) the patient; or
  - (c) a person specified in paragraph 1(2) acting on the patient's behalf.
- (6) If a contractor is unable to complete the course of the treatment which has been commenced for reasons beyond its control, it shall give notice to the Relevant Body of the extent of the treatment so provided and the reason for his inability to complete the remainder.

### **Treatment plans**

8.—(1) Subject to sub-paragraph (5), where the contractor agrees to provide a course of treatment to a patient, it shall, at the time of the initial examination and assessment of that patient, ensure that the patient is provided with a treatment plan on a form supplied for that purpose by the Relevant Body which shall specify—

- (a) the name of the patient;
- (b) the name of the contractor;
- (c) particulars of the places where the patient will receive services;
- (d) the telephone number at which the contractor may be contacted during normal surgery hours;
- (e) details of the services (if any) which are, at the date of the examination, considered necessary to secure the oral health of the patient;
- (f) the NHS charge, if any, in respect of those services if provided pursuant to the agreement; and
- (g) any proposals the contractor may have for private services as an alternative to the services proposed under the agreement, including particulars of the cost to the patient if he were to accept the provision of private services.

(2) If the patient, having considered the treatment plan provided pursuant to sub-paragraph (1), decides to accept the provision of private services in place of all or part of services under the agreement, the contractor shall ensure that the patient signs the treatment plan in the appropriate place to indicate that he has understood the nature of private services to be provided and his acceptance of those services.

(3) Where the services included in the treatment plan under this paragraph need to be varied, the contractor shall provide the patient with a revised treatment plan in accordance with sub-paragraph (1).

(4) Subject to paragraph 7(5), the contractor shall provide the services which are detailed in the treatment plan, or where the treatment plan is revised, the revised treatment plan.

(5) The obligation to provide a treatment plan under this paragraph shall not apply to a Band 1 course of treatment or a charge exempt course of treatment unless—

- (a) the contractor is providing privately any part of that course of treatment pursuant to paragraph 11; or
- (b) the patient has requested that he be provided with written details of the course of treatment to be provided or that has been provided to him, whether or not he specifically requests a treatment plan.

(6) Where a patient requests the contractor to provide him with a summary of the care and treatment provided under the treatment plan because he intends to receive services from another contractor, the contractor shall provide him with such a summary as he considers appropriate

(including details of the care and treatment which could not easily be observed on visual examination).

(7) The summary referred to in sub-paragraph (6) shall be supplied to the patient on a form—

(a) supplied for that purpose by the Relevant Body; or

(b) in the case where the contractor is the Primary Care Trust, the form that it supplies for that purpose to other contractors,

within 28 days of that request.

### **Completion of courses of treatment**

9.—(1) The contractor shall indicate—

(a) on the form supplied by the Relevant Body; or

(b) in the case where the contractor is a Primary Care Trust, on the form that it supplies to other contractors,

pursuant to paragraph 39 whether the course of treatment was completed, and if the course of treatment was not completed, provide the reason for the failure to complete the course of treatment.

(2) If the Relevant Body—

(a) determines that the number of courses of treatment provided by the contractor which have not been completed is excessive; and

(b) does not consider that the reasons given by the contractor for the failure to complete the courses of treatment are satisfactory,

it shall be entitled to exercise its powers under paragraph 59(2) on the grounds that the contractor is not, pursuant to paragraph 7(2), using its best endeavours to ensure courses of treatment are completed.

### **Referral to another contractor, a hospital or other relevant service provider for advanced mandatory, domiciliary or sedation services**

10.—(1) Where a patient requires advanced mandatory services, domiciliary services or sedation services that are not provided under the agreement by the contractor, it shall, if the patient agrees, refer that patient in accordance with sub-paragraph (2) for the provision of a referral service by an alternative contractor, a hospital or other relevant service provided under Part 1 of the Act.

(2) In referring a patient pursuant to sub-paragraph (1), the contractor shall provide—

(a) to the patient being referred, a referral notice on a form supplied for that purpose by the Relevant Body (or where the contractor is the Primary Care Trust, the form it supplies to other contractors for that purpose) which shall specify the services detailed on the treatment plan which will be carried out by the alternative contractor, hospital or other relevant service provider; and

(b) to the alternative contractor, hospital or other relevant service provider, either at the time of referral or as soon as reasonably practicable thereafter—

(i) a copy of the treatment plan provided to the patient pursuant to paragraph 8;

(ii) a copy of the referral notice; and

(iii) a statement of the amount paid to it, or due to be paid to it, by the patient under the NHS Charges Regulations in respect of the course of treatment during which the referral is made.

(3) Where the patient notifies the contractor, whether verbally or in writing, that he does not wish to be referred to the alternative contractor, hospital or other relevant service provider selected by the

contractor, the contractor shall, if requested to do so by the patient, use its best endeavours to refer the patient to another suitable contractor, hospital or other relevant service provider under Part 1 of the Act for the provision of the referral service.

### **Mixing of services provided under the agreement with private services**

**11.**—(1) Subject to sub-paragraph (2) and the requirements in paragraphs 2 (referral services) and 6 (orthodontic treatment plans) of Schedule 1 and paragraph 8(1)(g) of this Schedule, a contractor may, with the consent of the patient, provide privately any part of a course of treatment or orthodontic course of treatment for that patient, including in circumstances where that patient has been referred to the contractor for a referral service.

(2) A contractor may—

- (a) not provide privately or under the agreement treatment that involves the administration of general anaesthesia or the provision of sedation; and
- (b) in the case of an orthodontic course of treatment provide—
  - (i) the case assessment wholly privately or wholly under the agreement; and
  - (ii) the orthodontic treatment wholly privately or wholly under the agreement.

(3) A contractor shall not, with a view to obtaining the agreement of a patient to undergo services privately—

- (a) advise a patient that the services which are necessary in his case are not available from the contractor under the agreement; or
- (b) seek to mislead the patient about the quality of the services available under the agreement.

(4) In sub-paragraph (2)(a), “provision of sedation” means the provision of one or more drugs to a patient in order to produce a state of depression of the central nervous system to enable treatment to be carried out.

### **Repair or replacement of restorations**

**12.**—(1) Subject to sub-paragraph (5), where a restoration specified in sub-paragraph (2) needs to be repaired or replaced the contractor shall repair or replace the restoration at no charge to the patient.

(2) The restorations referred to in sub-paragraph (1) are any filling, root filling, inlay, porcelain veneer or crown provided by the contractor to a patient in the course of providing services under the agreement, including referral services, which, within the relevant period, has to be repaired or replaced to secure oral health.

(3) The repair or replacement of a restoration specified in sub-paragraph (2) is a banded course of treatment for the purposes of calculating the number of units of dental activity and paragraph 1 of Schedule 2 shall apply notwithstanding that no charge is made or recovered in accordance with the NHS Charges Regulations.

(4) The band in which the restoration specified in sub-paragraph (2) falls shall be determined in accordance with the NHS Charges Regulations.

(5) Sub-paragraph (1) shall not apply where—

- (a) within the relevant period, a person other than the contractor has provided treatment on the tooth in respect of which the restoration was provided;
- (b) the contractor advised the patient at the time of the restoration and indicated on the patient record that—
  - (i) the restoration was intended to be temporary in nature; or

- (ii) in its opinion, a different form of restoration was more appropriate to secure oral health but, notwithstanding that advice, the patient nevertheless requested the restoration which was provided;
  - (c) in the opinion of the contractor, the condition of the tooth in respect of which the restoration was provided is such that the restoration cannot satisfactorily be repaired or replaced and different treatment is now required; or
  - (d) the repair or replacement is required as a result of trauma.
- (6) In this paragraph “the relevant period” means the 12 month period beginning on the date on which the restoration was provided, and ceasing twelve months after that date.

### **Premises, facilities and equipment**

**13.—**(1) The contractor shall ensure that the premises used for the provision of services under the agreement are—

- (a) suitable for the delivery of those services; and
- (b) sufficient to meet the reasonable needs of the contractor’s patients.

(2) The obligation in sub-paragraph (1) includes providing proper and sufficient waiting-room accommodation for patients.

(3) The contractor shall provide, in relation to all of the services to be provided under the agreement, such other facilities and equipment as are necessary to enable it to properly perform that service.

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

### **Telephone services**

**14.—**(1) The contractor shall not be a party to any contract or other arrangement under which the number for telephone services to be used by—

- (a) patients to contact the practice for any purpose related to the agreement; or
- (b) any other person to contact the practice in relation to services provided as part of the health service,

starts with the digits 087, 090 or 091 or consists of a personal number, unless the service is provided free to the caller.

(2) In this paragraph, “personal number” means a telephone number which starts with the number 070 followed by a further 8 digits.

### **National Institute for Clinical Excellence guidance**

**15.** The contractor shall provide services under the agreement in accordance with any relevant guidance that is issued by the National Institute for Clinical Excellence<sup>(2)</sup>, in particular the guidance entitled “Dental recall - Recall interval between routine dental examinations”<sup>(3)</sup>.

### **Infection control**

**16.** The contractor shall ensure that it has appropriate arrangements for infection control and decontamination.

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(2) The National Institute for Clinical Excellence is established as a Special Health Authority under section 11 of the Act.

(3) This guidance is available from NICE’s website, [www.nice.org.uk](http://www.nice.org.uk).

**Treatment under general anaesthesia: prohibition**

17.—(1) Subject to sub-paragraph (2), the contractor shall not provide any services under the agreement that involve the provision of general anaesthesia.

(2) Where the contractor is a Primary Care Trust, NHS Foundation Trust or an NHS Trust, that contractor may provide general anaesthesia in accordance with guidance issued by the General Dental Council in “Standards for Dental Professions”(4).

**PART 3****SUPPLY OF DRUGS AND PRESCRIBING****General**

18. The contractor shall ensure that any prescription form for listed drugs, medicines or appliances issued by a prescriber complies as appropriate with the requirements in this Part.

**Supply of drugs**

19.—(1) A prescriber may supply to a patient such listed drugs, medicines or appliances as are required for immediate use before the issue of a prescription for such drugs, medicines or appliances in accordance with paragraph 20.

(2) A prescriber may personally administer to a patient any drug or medicine required for the treatment of that patient.

**Issue of prescription forms**

20.—(1) A prescriber shall order listed drugs, medicines or appliances (other than those supplied under paragraph 19) as are needed for the treatment of any patient to whom it is providing services under the agreement by issuing to the patient a prescription form.

(2) The prescription form shall—

- (a) be signed by the prescriber; and
- (b) be issued separately to each patient to whom the contractor is providing services under the agreement,

and a separate prescription form shall be issued for each patient.

(3) For the purposes of this paragraph, “prescription form” means a form that—

- (a) is supplied for the purposes of paragraph (1) by the Primary Care Trust; or
- (b) in the case where the contractor is a Primary Care Trust, is supplied by that Primary Care Trust to other contractors for the purposes of paragraph (1).

**Excessive prescribing**

21. The contractor shall not prescribe drugs, medicines or appliances whose cost or quantity, in relation to any patient, is, by reason of the character of the drug, medicine or appliance in question, in excess of that which was reasonably necessary for the proper treatment of that patient.

(4) <http://www.gdc-uk.org/News+publications+and+events/Publications/Guidance+documents?Standards+for+dental+professionals.htm>.



## PART 4

### PERSONS WHO PERFORM SERVICES

#### Dental practitioners

**22.** A dental practitioner<sup>(5)</sup> may perform dental services under the agreement provided he is—

- (a) included in a dental performers list for a Primary Care Trust in England; and
- (b) his inclusion in that list is not subject to a suspension.

#### Dental care professionals

**23.**—(1) Prior to the coming into force of the first regulations under section 36A(2) of the Dentists Act<sup>(6)</sup> (professions complementary to dentistry)—

- (a) a dental hygienist; or
- (b) a dental therapist,

may perform dental services under the agreement provided he is enrolled in the appropriate register established in accordance with the Dental Auxiliaries Regulations 1986<sup>(7)</sup>.

(2) Upon the coming into force of the first regulations under section 36A(2) of the Dentists Act—

- (a) a dental hygienist;
- (b) a dental therapist; or
- (c) a professional or member of a class as specified in regulations made under section 36A(2) of the Dentists Act,

may perform dental services under the agreement provided he is—

- (i) a dental care professional; and
- (ii) his registration in the dental care professional register established under section 36B of the Dentists Act<sup>(8)</sup> is not subject to a suspension.

#### Performers: further requirements

**24.**—(1) No health care professional or other person other than one to whom paragraph 23 applies shall perform clinical services under the agreement unless he is appropriately registered with his relevant professional body and his registration is not subject to a suspension.

(2) Where—

- (a) the registration of a dental practitioner, dental care professional or other health care professional; or
- (b) a dental practitioner's inclusion in a dental performers list,

is subject to conditions, the contractor shall ensure compliance with those conditions in so far as they are relevant to the agreement.

(3) No health care professional or other person shall perform any clinical services under the agreement unless he has such clinical experience and training as are necessary to enable him properly to perform such services.

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(5) The term dental practitioner is defined in section 128 of the Act as a person registered in the dentists register under the Dentists Act.

(6) Section 36A is prospectively inserted into the Dentists Act by article 29 of the Dentists Act Order.

(7) S.I. 1986/887; relevant amending instruments are S.I. 1999/3460 and 2002/1671.

(8) Section 36B is prospectively inserted into the Dentists Act by article 29 of the Dentists Act Order.

**Conditions for employment and engagement: dental practitioners performing dental services**

**25.—**(1) A contractor shall not employ or engage a dental practitioner to perform dental services under the agreement unless—

- (a) that practitioner has provided it with the name and address of the Primary Care Trust on whose dental performers list he appears; and
- (b) the contractor has checked that the practitioner meets the requirements in paragraph 22.

(2) Where the employment or engagement of a dental practitioner is urgently needed and it is not possible to check the matters referred to in paragraph 22 in accordance with sub-paragraph (1) (b) before employing or engaging him, he may be employed or engaged on a temporary basis for a single period of up to seven days whilst such checks are undertaken.

**Conditions for employment and engagement: persons performing dental services other than dental practitioners**

**26.—**(1) The contractor shall not employ or engage a dental care professional to perform dental services unless it has taken reasonable steps to satisfy itself that he has the clinical experience and training necessary to enable him to properly perform dental services and—

- (a) prior to the coming into force of the first regulations under section 36A(2) of the Dentists Act, the contractor has checked that his name is on the roll of the appropriate register established in accordance with the Dental Auxiliaries Regulations 1986; and
- (b) from the coming into force of the first regulations under section 36A(2) of the Dentists Act, the contractor has checked that—
  - (i) his name is included in the register of dental care professionals; and
  - (ii) his registration in the dental care professional register is not subject to a suspension.

(2) Where the employment or engagement of a person specified in sub-paragraph (1) is urgently needed and it is not possible to check the references referred to in sub-paragraph (1) (where it applies) before employing or engaging him, he may be employed or engaged on a temporary basis for a single period of up to seven days whilst such checks are undertaken.

(3) When considering a person's experience and training for the purposes of sub-paragraph (1), the contractor shall have regard in particular to—

- (a) any post-graduate or post-registration qualification held by that person; and
- (b) any relevant training undertaken by him and any relevant clinical experience gained by him.

**Conditions for employment and engagement: all persons performing dental services**

**27.—**(1) The contractor shall not employ or engage a person to perform dental services under the agreement unless—

- (a) that person has provided two clinical references that relate to two recent posts (which may include any current post) exercising the profession in which he seeks employment or engagement with the contractor which lasted for three months or more without a significant break, or where this is not possible, that person has provided a full explanation and alternative referees; and
- (b) the contractor has checked and is satisfied with the references.

(2) Where the employment or engagement of a person falling within sub-paragraph (1) is urgently needed and it is not possible for the contractor to check the references in accordance with sub-paragraph (1)(b) before employing or engaging him, he may be employed or engaged on a temporary basis for a single period of up to 14 days whilst his references are checked and considered, and for

an additional period of a further seven days if the contractor believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where the contractor employs or engages the same person on more than one occasion within a period of three months, it may rely on the references provided on the first occasion, provided that those references are not more than 12 months old.

#### **Conditions for employment or engagement: persons assisting in the provision of services under the agreement**

**28.**—(1) Before employing or engaging any person to assist it in the provision of services under the agreement, the contractor shall take reasonable care to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which he is to be employed or engaged.

(2) The duty imposed by sub-paragraph (1) is in addition to the duties imposed by paragraphs 25 to 27.

(3) When considering the competence and suitability of any person for the purpose of sub-paragraph (1), the contractor shall have regard, in particular, to—

- (a) that person's academic and vocational qualifications;
- (b) his education and training; and
- (c) his previous employment or work experience.

#### **Training**

**29.**—(1) The contractor shall ensure that for any dental practitioner or dental care professional who is—

- (a) performing dental services under the contract; or
- (b) employed or engaged to assist in the performance of such services,

arrangements are in place for the purpose of maintaining and updating his skills and knowledge in relation to the services which he is performing or assisting in performing.

(2) The contractor shall afford to each employee reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.

#### **Level of skill**

**30.** The contractor shall carry out its obligations under the contract with reasonable care and skill.

#### **Appraisal and assessment**

**31.** The contractor shall ensure that any dental practitioner performing services under the agreement—

- (a) participates in the appraisal system (if any) provided by the Relevant Body or where the contractor is a Primary Care Trust, by it, unless he participates in the appraisal system provided by another health service body; and
- (b) co-operates with an assessment by the NPSA when requested to do so by the Relevant Body, or where the contractor is a Primary Care Trust, by that Trust.

#### **Sub-contracting of clinical matters**

**32.**—(1) The contractor shall not sub-contract any of its rights or duties under the agreement to any person in relation to clinical matters unless—

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- (a) it has taken reasonable steps to satisfy itself that—
    - (i) it is reasonable in all the circumstances; and
    - (ii) that the person is qualified and competent to provide the service; and
  - (b) it is satisfied in accordance with paragraphs 79 and 80 that the sub-contractor holds adequate insurance.
- (2) Where the contractor sub-contracts any of its rights or duties under the agreement in relation to clinical matters, it shall—
- (a) inform the Relevant Body of the sub-contract as soon as is reasonable practicable; and
  - (b) provide the Relevant Body with such information in relation to the sub-contract as it reasonably requests.
- (3) Where the contractor sub-contracts clinical services in accordance with sub-paragraph (1), the parties to the agreement shall be deemed to have agreed a variation to the agreement which has the effect of adding to the list of the contractor's premises any premises which are to be used by the sub-contractor for the purpose of the sub-contract and paragraph 60 shall not apply.
- (4) A contract with a sub-contractor must prohibit the sub-contractor from sub-contracting the clinical services it has agreed with the contractor to provide.

## 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 the Relevant Body or, where the contractor is a Primary Care Trust, collated by that Trust 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>(9)</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.

### **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);
  - (b) such information relating to NHS Charges—
    - (i) as is supplied by the Relevant Body for the purposes of providing information to patients; or
    - (ii) in the case where the contractor is a Primary Care Trust, that it supplies to other contractors for this purpose; 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.

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(9) [S.I. 2002/618](#).

**Provision of and access to information: the Relevant Body**

- 36.**—(1) The contractor shall, at the request of the Relevant Body—
- (a) produce to the Relevant Body or to a person authorised in writing by the Relevant Body in such format, and at such intervals or within such time, as the Relevant Body specifies; or
  - (b) allow the Relevant Body, 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 the Relevant Body for the purposes of or in connection with the agreement; and
  - (b) any other information which is reasonably required in connection with the Relevant Body's functions,
- and includes the contractor's patient records.

**Requests for information from Patients' Forums**

- 37.**—(1) Subject to sub-paragraph (2), where the contractor (other than a Primary Care Trust) receives a written request from the Patients' Forum established for the area of the Primary Care Trust to produce any information which appears to the Forum to be necessary for the effective carrying out of its functions, it shall comply with that request promptly and in any event no later than the twentieth working day following the date the request was made.
- (2) The contractor shall not be required to produce information under sub-paragraph (1) which—
- (a) is confidential and relates to a living individual, unless at least one of the conditions specified in sub-paragraph (3) applies; or
  - (b) is prohibited from disclosure by or under any enactment or any ruling of a court of competent jurisdiction or is protected by the common law, unless sub-paragraph (4) applies.
- (3) The conditions referred to in sub-paragraph (2)(a) are—
- (a) the information can be disclosed in a form from which the identity of the individual cannot be ascertained; or
  - (b) the individual consents to the information being disclosed.
- (4) This sub-paragraph applies where—
- (a) the prohibition of the disclosure of information arises because the information is capable of identifying an individual; and
  - (b) the information can be disclosed in a form from which the identity of the individual cannot be ascertained.
- (5) In a case where the information falls within—
- (a) sub-paragraph (2)(a) and the condition in sub-paragraph (3)(a) applies; or
  - (b) sub-paragraph (2)(b) and sub-paragraph (4) applies,
- a Patients' Forum may require the contractor to disclose the information in a form from which the identity of the individual concerned cannot be ascertained.

**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 the Relevant Body 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 the Relevant Body 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 the Relevant Body 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 the Relevant Body to make such inquiry on its behalf.

**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,

send to the Relevant Body, on a form supplied by the Primary Care Trust, the information specified in paragraph (3).

(2) In the case where the contractor is the Primary Care Trust, that Trust shall collate the information specified in paragraph (3).

(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
- (d) in the case of a patient exempt from NHS Charges and where such information is not submitted electronically, the written declaration form and note of evidence in support of that declaration.

**Annual report and review**

**40.**—(1) The Relevant Body 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 that Body.

(2) Once the Relevant Body has provided the report referred to in sub-paragraph (1), the Relevant Body shall arrange with the contractor an annual review of its performance in relation to the agreement.

(3) The Relevant Body 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.

**Notifications to the Relevant Body**

**41.**—(1) In addition to any requirements of notification elsewhere in these Regulations, the contractor shall notify the Relevant Body 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 the Relevant Body'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 the Relevant Body in writing within 28 days of any occurrence requiring a change in the information about it published by the Relevant Body in accordance with regulations made under section 16CA(3) of the Act<sup>(10)</sup> (primary dental services).

(3) The contractor shall give notice in writing to the Relevant Body 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.

**Notice provisions specific to an agreement with a qualifying body**

**42.** Where a qualifying body is a party to the agreement, it shall give notice in writing to the Relevant Body 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<sup>(11)</sup> (definition of inability to pay debts).

<sup>(10)</sup> Section 16CA was inserted into the Act by section 170 of the 2003 Act.

<sup>(11)</sup> 1986 c. 45.



### **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.

### **Entry and inspection by the Relevant Body**

**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 the Relevant Body 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 45 or 46, if—

- (a) the contractor has used its best endeavours to allow the Relevant Body, members of a Patients' Forum or the Commission for Healthcare Audit and Inspection 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.

### **Entry and inspection by members of Patients' Forums**

**45.** Subject to paragraph 44(3), the contractor shall allow members of a Patients' Forum authorised by or under regulation 3 of the Patients' Forums (Functions) Regulations 2003<sup>(12)</sup> to enter and inspect the practice premises for the purpose of any of the Forums' functions in accordance with that regulation.

### **Entry and inspection by the Commission for Healthcare Audit and Inspection**

**46.** Subject to paragraph 44(3), the contractor shall allow persons authorised by the Commission for Healthcare Audit and Inspection to enter and inspect premises in accordance with section 66 of the Health and Social Care (Community Health and Standards) Act 2003<sup>(13)</sup> (right of entry).

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(12) S.I. 2003/2124.

(13) 2003 c. 43.

## PART 6

### COMPLAINTS

#### Complaints procedure

**47.—**(1) The contractor shall establish and operate a complaints procedure to deal with any complaints in relation to any matter reasonably connected with the provision of services under the agreement which shall comply—

- (a) subject to sub-paragraph (b), with the requirements of paragraphs 48 to 50 and 52; or
  - (b) in the case where the contractor is a Primary Care Trust, with any directions made under section 17 of the Act.
- (2) The contractor shall take reasonable steps to ensure that patients are aware of—
- (a) the complaints procedure;
  - (b) the role of the Relevant Body and other bodies in relation to complaints about services under the agreement; and
  - (c) their right to assistance with any complaint from independent advocacy services provided under section 19A of the Act<sup>(14)</sup> (independent advocacy services).
- (3) The contractor shall take reasonable steps to ensure that the complaints procedure is accessible to all patients.

#### Making of complaints

**48.** A complaint may be made by or, with his consent, on behalf of a patient or former patient, who is receiving or has received services under the agreement, or—

- (a) where the patient is a child, by—
    - (i) either parent;
    - (ii) a person duly authorised by a local authority to whose care the child has been committed under the provisions of the Children Act 1989<sup>(15)</sup>; or
    - (iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of that Act; or
  - (b) where the patient is incapable of making a complaint, by a relative or other adult person who has an interest in his welfare.
- (2) Where a patient has died, a complaint may be made by a relative or other adult person who had an interest in his welfare or, where the patient falls within paragraph 48(a)(ii) or (iii) by the authority or a voluntary organisation.

#### Period for making complaints

- 49.—**(1) Subject to sub-paragraph (2), the period for making a complaint is—
- (a) six months beginning with the date on which the matter which is the subject of the complaint occurred; or
  - (b) six months beginning with the date on which the matter which is the subject of the complaint comes to the complainant's notice provided that the complaint is made no later than 12 months after the date on which the matter which is the subject of the complaint occurred.

<sup>(14)</sup> Section 19A was inserted by the Health and Social Care Act 2001 (c. 15), section 12.

<sup>(15)</sup> 1989 c. 41.

(2) Where a complaint is not made during the period specified in sub-paragraph (1), it shall be referred to the person nominated under paragraph 50(2)(a) and if he is of the opinion that—

- (a) having regard to all the circumstances of the case, it would have been unreasonable for the complainant to make the complaint within that period; and
- (b) notwithstanding the time that has elapsed since the date on which the matter which is the subject matter of the complaint occurred, it is still possible to investigate the complaint properly,

the complaint shall be treated as if it had been received during the period specified in sub-paragraph (1).

### **Further requirements for complaints procedures**

**50.—**(1) A complaints procedure shall also comply with the requirements set out in sub-paragraphs (2) to (6).

(2) The contractor must nominate—

- (a) a person (who need not be connected with the contractor and who, in the case of an individual, may be specified by his job title) to be responsible for the operation of the complaints procedure and the investigation of complaints; and
- (b) an individual who is a party to the agreement or other senior person associated with the contractor, to be responsible for the effective management of the complaints procedure and for ensuring that action is taken in the light of the outcome of any investigation.

(3) All complaints must be—

- (a) either made or recorded in writing;
- (b) acknowledged in writing within the period of three working days beginning with the day on which the complaint was made or, where that is not possible, as soon as reasonably practicable; and
- (c) properly investigated.

(4) Within the period of ten working days beginning with the day on which the complaint was received by the person specified under sub-paragraph (2)(a) or, where that is not possible, as soon as reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions.

(5) Where the investigation of the complaint requires consideration of the patient's dental records, the person specified in sub-paragraph (2)(a) must inform the patient or person acting on his behalf if the investigation will involve disclosure of information contained in those records to a person other than the contractor or an employee of the contractor.

(6) The contractor must keep a record of all complaints and copies of all correspondence relating to complaints for a period of at least two years from the date on which such complaints were made, but such records shall be kept separate from patients' dental records.

### **Co-operation with investigations**

**51.—**(1) The contractor (other than a Primary Care Trust) shall co-operate with—

- (a) any investigation of a complaint in relation to any matter reasonably connected with the provision of services under the agreement undertaken by—
  - (i) the Relevant Body; and
  - (ii) the Commission for Healthcare Audit and Inspection; and

- (b) any investigation of a complaint by an NHS body or local authority which relates to a patient or former patient of the contractor.
- (2) In sub-paragraph (1)—
  - “NHS body” means a Primary Care Trust, an NHS trust, an NHS foundation trust, a Strategic Health Authority, a Local Health Board, a Health Board, a Health and Social Services Board, a Health and Social Services Trust or, a Health Board or Special Health Board constituted under section 2 of the National Health Service (Scotland) Act 1978<sup>(16)</sup>;
  - “local authority” means—
    - (a) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970<sup>(17)</sup> (local authorities);
    - (b) the Council of the Isles of Scilly; or
    - (c) a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994<sup>(18)</sup> (constitution of councils).
- (3) The co-operation required by sub-paragraph (1) includes—
  - (a) answering questions reasonably put to the contractor by the Relevant Body;
  - (b) providing any information relating to the complaint reasonably required by the Relevant Body; and
  - (c) attending any meeting to consider the complaint (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given) if the contractor’s presence at the meeting is reasonably required by the Relevant Body.

#### **Provision of information**

**52.** The contractor (other than a Primary Care Trust) shall inform the Relevant Body, at such intervals as the Relevant Body requires, of the number of complaints it has received under the procedure established in accordance with this Part.

## **PART 7**

### **DISPUTE RESOLUTION**

#### **Local resolution of agreement disputes**

**53.** In the case of any dispute arising out of, or in connection with, the agreement, the contractor and the Relevant Body must make every reasonable effort to communicate and co-operate with each other with a view to resolving the dispute, before referring the dispute for determination in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings).

#### **Dispute resolution: non-NHS contracts**

**54.—(1)** In the case of an agreement which is not an NHS contract, any dispute arising out of or in connection with the agreement, except disputes about matters dealt with under the complaints procedure pursuant to Part 6 of this Schedule, may be referred for consideration and determination to the Secretary of State, if—

<sup>(16)</sup> 1978 c. 29.

<sup>(17)</sup> 1970 c. 42; section 1 was amended by the Local Government Act 1972 (c. 70), section 195; and by the Local Government (Wales) Act 1994 (c. 19), Schedule 10, paragraph 7.

<sup>(18)</sup> 1994 c. 39.

- (a) the Relevant Body so wishes and the contractor has agreed in writing; or
- (b) the contractor so wishes (even if the Relevant Body does not agree).
- (2) In the case of a dispute referred to the Secretary of State under sub-paragraph (1)—
  - (a) the procedure to be followed is the NHS dispute resolution procedure; and
  - (b) the parties agree to be bound by any determination made by the adjudicator.

### **NHS dispute resolution procedure**

**55.**—(1) The procedure specified in the following sub-paragraphs and paragraph 56 applies in the case of any dispute arising out of or in connection with the agreement which is referred to the Secretary of State—

- (a) in accordance with section 4(3) of the 1990 Act (where the agreement is an NHS contract); or
- (b) in accordance with paragraph 54(1) (where the agreement is not an NHS contract).
- (2) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) shall send to the Secretary of State a written request for dispute resolution which shall include or be accompanied by—
  - (a) the names and addresses of the parties to the dispute;
  - (b) a copy of the agreement; and
  - (c) a brief statement describing the nature and circumstances of the dispute.
- (3) Any party wishing to refer a dispute as mentioned in sub-paragraph (1) must send the request under sub-paragraph (2) within a period of three years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.
- (4) Where the dispute relates to an agreement which is not an NHS contract, the Secretary of State may determine the matter herself or, if she considers it appropriate, appoint a person or persons to consider and determine it<sup>(19)</sup>.
- (5) Before reaching a decision as to who should determine the dispute, either under sub-paragraph (4) or under section 4(5) of the 1990 Act, the Secretary of State shall, within the period of seven days beginning with the date on which a matter was referred to her, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter.
- (6) The Secretary of State shall give, with the notice given under sub-paragraph (5), to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.
- (7) The Secretary of State shall give a copy of any representations received from a party to the other party and shall in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.
- (8) Following receipt of any representations from the parties or, if earlier, at the end of the period for making such representations specified in the request sent under sub-paragraph (5) or (7), the Secretary of State shall, if she decides to appoint a person or persons to hear the dispute—
  - (a) inform the parties in writing of the name of the person or persons whom she has appointed; and

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<sup>(19)</sup> Where the dispute relates to a contract which is an NHS contract, section 4(5) of the 1990 Act applies.

- (b) pass to the person or persons so appointed any documents received from the parties under or pursuant to paragraph (2), (5) or (7).
- (9) For the purpose of assisting him in his consideration of the matter, the adjudicator may—
  - (a) invite representatives of the parties to appear before him to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which he wishes them to give special consideration; or
  - (b) consult other persons whose expertise he considers will assist him in his consideration of the matter.
- (10) Where the adjudicator consults another person under sub-paragraph (9)(b), he shall notify the parties accordingly in writing and, where he considers that the interests of any party might be substantially affected by the result of the consultation, he shall give to the parties such opportunity as he considers reasonable in the circumstances to make observations on those results.
- (11) In considering the matter, the adjudicator shall consider—
  - (a) any written representations made in response to a request under sub-paragraph (5), but only if they are made within the specified period;
  - (b) any written observations made in response to a request under sub-paragraph (7), but only if they are made within the specified period;
  - (c) any oral representations made in response to an invitation under sub-paragraph (9)(a);
  - (d) the results of any consultation under sub-paragraph (9)(b); and
  - (e) any observations made in accordance with an opportunity given under sub-paragraph (10).
- (12) In this paragraph, “specified period” means such period as the Secretary of State shall specify in the request, being not less than two, nor more than four weeks, beginning with the date on which the notice referred to is given, but the Secretary of State may, if she considers that there is good reason for doing so, extend any such period (even after it has expired) and, where she does so, a reference in this paragraph to the specified period is to the period as so extended.
- (13) Subject to the other provisions of this paragraph and paragraph 56, the adjudicator shall have wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

### **Determination of dispute**

- 56.**—(1) The adjudicator shall record his determination and the reasons for it in writing and shall give notice of the determination (including a record of the reasons) to the parties.
- (2) In the case of any dispute referred for determination in accordance with paragraph 54(1), subsection (8) of section 4 of the 1990 Act shall apply as that subsection applies in the case of any dispute referred for determination in accordance with subsection (3) of section 4 of that Act.

### **Interpretation of Part 7**

- 57.**—(1) In this Part, “any dispute arising out of, or in connection with, the agreement” includes any dispute arising out of, or in connection with, the termination of the agreement.
- (2) Any term of the agreement that makes provision in respect of the requirements in this Part shall survive even where the agreement has terminated.

## PART 8

### MID-YEAR REVIEW OF ACTIVITY UNDER AGREEMENTS

#### Mid-year reviews

**58.**—(1) This paragraph and paragraph 59 apply where services are to be provided under the agreement from 1st April in any financial year.

(2) In this paragraph and paragraph 59, references to requirements to provide units of dental activity or units of orthodontic activity are to such requirements under the terms of the agreement giving effect to regulation 13 (units of dental activity) or 14 (units of orthodontic activity).

(3) The Relevant Body shall, by 31st October in each financial year, determine the number of—

- (a) units of dental activity; or
- (b) units of orthodontic activity,

that the contractor has provided between 1st April and 30th September of that financial year based on the data provided to it by virtue of paragraph 39.

(4) Where the Relevant Body determines under sub-paragraph (3) that the contractor has, between 1st April and 30th September, provided less than 30 per cent of the total number of—

- (a) units of dental activity; or
- (b) units of orthodontic activity,

that it is required to provide in that financial year, sub-paragraph (5) shall apply.

(5) Where this sub-paragraph applies, the Relevant Body may—

- (a) notify the contractor that it is concerned about the level of activity provided under the agreement in the first half of the financial year, setting out—
  - (i) the number of units of dental activity or units of orthodontic activity (as the case may be) that it has determined that the contractor has provided; and
  - (ii) the percentage of the total number of units of dental activity or units of orthodontic activity (as the case may be) required to be provided during the financial year that the number in sub-paragraph (i) represents; and
- (b) require in that notification that the contractor participate in a mid-year review of its performance in relation to the agreement with the Relevant Body.

(6) Where a mid-year review is required by the Relevant Body under sub-paragraph (5), the Relevant Body and the contractor shall discuss at that review—

- (a) any written evidence the contractor puts forward to demonstrate that it has performed a greater number of units of dental activity or units of orthodontic activity during the first half of the financial year than those notified to it pursuant to sub-paragraph (5)(a)(i); and
- (b) any reasons that the contractor puts forward for the level of activity in the first half of the financial year.

(7) The Relevant Body shall prepare a draft record of the mid-year review for comment by the contractor and, having regard to such comments, shall produce a final written record of the review.

(8) A copy of the final record of the mid-year review shall be sent to the contractor.

#### Action the Relevant Body can take following a mid-year review

**59.**—(1) Where, following the mid-year review and the provision of the final record of that review to the contractor, the Relevant Body, having taken account of any evidence or reasons put

*Status: This is the original version (as it was originally made).*

forward by the contractor at that review, nevertheless has serious concerns that the contractor is unlikely to provide the number of—

- (a) units of dental activity; or
- (b) units of orthodontic activity,

that it is required to provide by the end of the financial year, the Relevant Body shall be entitled to take either or both of the steps specified in paragraph (2).

(2) The Relevant Body may—

- (a) require the contractor to comply with a written plan drawn up by the Relevant Body to ensure that the level of activity during the remainder of the financial year is such that the contractor will provide the number of units of dental activity or units of orthodontic activity it is required to provide; or
- (b) withhold monies payable under the agreement.

(3) The maximum amount that may be withheld under sub-paragraph (2)(b) is—

- (a) the amount that is payable under the agreement in respect of the number of units of dental activity or units of orthodontic activity required to be provided in a financial year, less
- (b) the amount that would be payable under the agreement as a relevant proportion of that amount if the contractor provided in the whole of the financial year only twice the number of units of dental activity or orthodontic activity that it provided between 1st April and 30th September.

(4) Nothing in this paragraph shall prevent the Relevant Body and the contractor agreeing to vary the contract in accordance with paragraph 61 to adjust—

- (a) the level of activity to be provided under the agreement; or
- (b) the monies to be paid by the Relevant Body to the contractor under the agreement.

(5) Where the Relevant Body withholds monies pursuant to paragraph (2), it shall ensure that it pays the withheld monies to the contractor as soon as possible following the end of the financial year where the contractor has—

- (a) provided the number of units of dental activity or units of orthodontic activity required to be provided; or
- (b) failed to provide that number of units of dental activity or units of orthodontic activity, but that failure amounts to 4 per cent or less of the total number of units of dental activity or units of orthodontic activity that ought to have been provided during that financial year (and therefore regulation 15 applies).

## PART 9

### VARIATION AND TERMINATION OF AGREEMENTS

**60.**—(1) Subject to paragraph 32(3), no amendment or variation shall have effect unless it is in writing and signed by or on behalf of the Relevant Body and the contractor.

(2) In addition to the specific provision made in paragraph 73, the Relevant Body may vary the agreement without the contractor's consent where it—

- (a) is reasonably satisfied that it is necessary to vary the agreement so as to comply with the Act, any regulations made pursuant to that Act, or any direction given by the Secretary of State pursuant to that Act; and
- (b) notifies the contractor in writing of the wording of the proposed variation and the date upon which that variation is to take effect,



and, where it is reasonably practicable to do so, the date that the proposed variation is to take effect shall be not less than 14 days after the date on which the notice under paragraph (b) is served on the contractor.

#### **Variation of an agreement: activity under the agreement**

**61.**—(1) Where the contractor or the Relevant Body is of the opinion that there needs to be a variation to the number of—

- (a) units of dental activity; or
- (b) units of orthodontic activity,

to be provided under the agreement, sub-paragraphs (2) and (3) shall apply.

(2) The contractor or the Relevant Body shall notify the other party to the agreement in writing of its opinion of the need for a variation, specifying in that notice the variation that it considers necessary, together with its reasons.

(3) Following service of the notice referred to in sub-paragraph (2), both parties shall use their best endeavours to communicate and co-operate with each other with a view to determining what (if any) variation should be made to the number of—

- (a) units of dental activity; or
- (b) units of orthodontic activity,

and any related variations to the agreement, including to the monies to be paid to the contractor under the agreement, and shall where appropriate effect the variation in accordance with paragraph 60.

#### **Termination by agreement**

**62.** The Relevant Body and the contractor may agree in writing to terminate the agreement, and if the parties so agree, they shall agree the date upon which that termination should take effect and any further terms upon which the agreement should be terminated.

#### **Termination on the death of an individual**

**63.**—(1) Where the agreement is with a single individual and that individual dies, the agreement shall terminate at the end of the period of seven days after the date of his death unless, before the end of that period—

- (a) subject to sub-paragraph (2), the Relevant Body has agreed in writing with that individual's personal representatives that the agreement should continue for a further period, not exceeding three months after the end of the period of seven days; and
- (b) that individual's personal representatives have confirmed in writing to the Relevant Body that they are employing or engaging one or more dental practitioners to assist in the provision of dental services under the agreement throughout the period for which it continues.

(2) Where the Relevant Body is of the opinion that another individual may wish to enter into an agreement in respect the mandatory services which were provided by the deceased, the three month period referred to in sub-paragraph (1)(a) may be extended by a period not exceeding six months as may be agreed.

(3) Sub-paragraph (1) does not affect any other rights to terminate the agreement which the Relevant Body may have under paragraphs 67 to 71.

**Termination by the contractor**

64.—(1) A contractor may terminate the agreement by serving notice in writing on the Relevant Body at any time.

(2) Where a contractor serves notice pursuant to sub-paragraph (1), the agreement shall terminate three months after the date on which the notice is served (“the termination date”), save that if the termination date is not the last calendar day of a month, the agreement shall instead terminate on the last calendar day of the month in which the termination date falls.

(3) This paragraph and paragraph 65 are without prejudice to any other rights to terminate the agreement that the contractor may have.

**Late payment notices**

65.—(1) The contractor may give notice in writing (a “late payment notice”) to the Relevant Body if the Relevant Body has failed to make any payments due to the contractor in accordance with a term of the agreement that has the effect specified in regulation 17, and the contractor shall specify in the late payment notice the payments that the Relevant Body has failed to make in accordance with that regulation.

(2) Subject to sub-paragraph (3), the contractor may, at least 28 days after having served a late payment notice, terminate the agreement by a further written notice if the Relevant Body has still failed to make the payments that were due to the contractor and that were specified in the late payment notice served on the Relevant Body pursuant to sub-paragraph (1).

(3) If, following receipt of a late payment notice, the Relevant Body refers the matter to the NHS dispute resolution procedure within 28 days of the date upon which it is served with the late payment notice, and it notifies the contractor in writing that it has done so within that period of time, the contractor may not terminate the agreement pursuant to sub-paragraph (2) until—

- (a) there has been a determination of the dispute pursuant to paragraph 56 and that determination permits the contractor to terminate the agreement; or
- (b) the Relevant Body ceases to pursue the NHS dispute resolution procedure,
- (c) whichever is the sooner.

**Termination by the Relevant Body: general provisions**

66. The Relevant Body may only terminate the agreement in accordance with the provisions in this Part.

**Termination by the Relevant Body: notice**

67.—(1) The Relevant Body may terminate the agreement by serving notice in writing on the contractor at any time.

(2) Where a notice is served pursuant to sub-paragraph (1), the agreement shall terminate on the date provided for in the agreement.

**Termination by the Relevant Body for the provision of untrue etc. information**

68. The Relevant Body may serve notice in writing on the contractor terminating the agreement forthwith, or from such date as may be specified in the notice if, after the agreement has been entered into, it comes to the attention of the Relevant Body that written information provided to it by the contractor before the agreement was entered into in relation to the conditions set out in regulation 4 or 5 (and compliance with those conditions) was, when given, untrue or inaccurate in a material respect.

### **Termination by the Relevant Body on grounds of suitability etc.**

**69.**—(1) The Relevant Body may serve notice in writing on the contractor terminating the agreement forthwith, or from such date as may be specified in the notice if—

- (a) in the case of an agreement with an individual as a party, that individual;
- (b) in the case of an agreement with a qualifying body—

- (i) the qualifying body; or
  - (ii) any director, chief executive or secretary of the qualifying body,

falls within sub-paragraph (2) during the existence of the agreement.

(2) A person falls within this sub-paragraph if—

- (a) he or it is the subject of a national disqualification;
- (b) subject to sub-paragraph (3), he or it is disqualified or suspended (other than by an interim suspension order or direction pending an investigation or a suspension on the grounds of ill-health) from practising by any licensing body anywhere in the world;
- (c) subject to sub-paragraph (4), he has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body unless before the Relevant Body has served a notice terminating the agreement pursuant to this paragraph, he is employed by the health service body that dismissed him or by another health service body;
- (d) he or it is removed from, or refused admission to, a primary care list by reason of inefficiency, fraud or unsuitability (within the meaning of section 49F(2), (3) and (4) of the Act<sup>(20)</sup> respectively) unless his name has subsequently been included in such a list;
- (e) he has been convicted in the United Kingdom of—
  - (i) murder; or
  - (ii) a criminal offence other than murder, committed on or after 14th December 2001, and has been sentenced to a term of imprisonment of over six months;
- (f) subject to sub-paragraph (5), he has been convicted outside the United Kingdom of an offence—
  - (i) which would, if committed in England and Wales, constitute murder; or
  - (ii) committed on or after 14th December 2001, which would if committed in England and Wales, constitute a criminal offence other than murder, and been sentenced to a term of imprisonment of over six months;
- (g) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933<sup>(21)</sup> (offences against children and young persons with respect to which special provisions of this Act apply) or Schedule 1 to the Criminal Procedure (Scotland) Act 1995<sup>(22)</sup> (offences against children under the age of 17 years to which special provisions apply);
- (h) he or it has—
  - (i) been adjudged bankrupt or had sequestration of his estate awarded unless (in either case) he has been discharged or the bankruptcy order has been annulled;

<sup>(20)</sup> Section 49F was inserted into the Act by section 25 of the 2001 Act and amended by the 2002 Act, Schedule 3, paragraph 21; and the 2003 Act, Schedule 14, Part 2.

<sup>(21)</sup> 1933 c. 12; as amended by the Domestic Violence, Crime and Victims Act 2004 (c. 28), section 58(1), Schedule 10, paragraph 2; the Sexual Offences Act 2003 (c. 42), section 139 and Schedule 6, paragraph 7; the Criminal Justice Act 1988 (c. 33), section 170 and Schedule 15, paragraph 8 and Schedule 16, paragraph 16; and the Sexual Offences Act 1956 (c. 69), sections 48 and 51 and Schedules 3 and 4; as modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

<sup>(22)</sup> 1995 c. 46.

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- (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986<sup>(23)</sup>, unless that order has ceased to have effect or has been annulled;
  - (iii) made a composition or arrangement with, or granted a trust deed for, his or its creditors unless he or it has been discharged in respect of it; or
  - (iv) been wound up under Part 4 of the Insolvency Act 1986;
  - (i) there is—
    - (i) an administrator, administrative receiver or receiver appointed in respect of it; or
    - (ii) an administration order made in respect of it under Schedule B1 to the Insolvency Act 1986<sup>(24)</sup>;
  - (j) he has been—
    - (i) removed from the office of charity trustee or trustee for a charity by an order made by the Charity Commissioners or the High Court on the grounds of any misconduct or mismanagement in the administration of the charity for which he was responsible or to which he was privy, or which he by his conduct contributed to or facilitated; or
    - (ii) removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990<sup>(25)</sup> (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of any body;
  - (k) he is subject to a disqualification order under the Company Directors Disqualification Act 1986<sup>(26)</sup>, the Companies (Northern Ireland) Order 1986<sup>(27)</sup> or to an order made under section 429(2)(b) of the Insolvency Act 1986 (failure to pay under county court administration order); or
  - (l) he has refused to comply with a request by the Relevant Body for him to be medically examined on the ground that it is concerned that he is incapable of adequately providing services under the agreement.
- (3) A Relevant Body shall not terminate the agreement pursuant to sub-paragraph (2)(b) where it is satisfied that the disqualification or suspension imposed by a licensing body outside the United Kingdom does not make the person unsuitable to be—
- (a) a contractor; or
  - (b) in the case of an agreement with a qualifying body, a director, chief executive or secretary of the corporation.
- (4) A Relevant Body shall not terminate the agreement pursuant to sub-paragraph (2)(c)—
- (a) until a period of at least three months has elapsed since the date of the dismissal of the person concerned; or
  - (b) if, during the period of time specified in paragraph (a), the person concerned brings proceedings in any competent tribunal or court in respect of his dismissal, until proceedings before that tribunal or court are concluded,
- and the Relevant Body may only terminate the agreement at the end of the period specified in paragraph (b) if there is no finding of unfair dismissal.
- (5) A Relevant Body shall not terminate the agreement pursuant to sub-paragraph (2)(f) where it is satisfied that the conviction does not make the person unsuitable to be—

<sup>(23)</sup> 1986 c. 45. Schedule 4A was inserted by section 257 of, and Schedule 3 to, the Enterprise Act 2002 (c. 40).

<sup>(24)</sup> Schedule B1 was inserted by section 248 of, and Schedule 16 to, the Enterprise Act 2002.

<sup>(25)</sup> 1990 c. 40.

<sup>(26)</sup> 1986 c. 46; as amended by the Insolvency Act 2000 (c. 39).

<sup>(27)</sup> S.I. 1986/1032 (N.I.6).

- (a) a contractor; or
- (b) in the case of an agreement with a qualifying body, a director, chief executive or secretary of that qualifying body.

**Termination by the Relevant Body: patient safety and material financial loss**

**70.** The Relevant Body may serve notice in writing on the contractor terminating the agreement forthwith or with effect from such date as may be specified in the notice if—

- (a) the contractor has breached the agreement and as a result of that breach, the safety of the contractor’s patients is at serious risk if the agreement is not terminated; or
- (b) the contractor’s financial situation is such that the Relevant Body considers that the Relevant Body is at risk of material financial loss.

**Termination by the Relevant Body: remedial notices and breach notices**

**71.—**(1) Where a contractor has breached the agreement other than as specified in paragraphs 68 to 70 and the breach is capable of remedy, the Relevant Body shall, before taking any action it is otherwise entitled to take by virtue of the agreement, serve a notice on the contractor requiring it to remedy the breach (“remedial notice”).

(2) A remedial notice shall specify—

- (a) details of the breach;
- (b) the steps the contractor must take to the satisfaction of the Relevant Body in order to remedy the breach; and
- (c) the period during which the steps must be taken (“the notice period”).

(3) The notice period shall, unless the Relevant Body is satisfied that a shorter period is necessary to—

- (a) protect the safety of the contractor’s patients; or
- (b) protect itself from material financial loss,

be no less than 28 days from the date that notice is given.

(4) Where a Relevant Body is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the Relevant Body may terminate the agreement with effect from such date as the Relevant Body may specify in a further notice to the contractor.

(5) Where a contractor has breached the agreement otherwise than as specified in paragraphs 68 to 70 and the breach is not capable of remedy, the Relevant Body may serve notice on the contractor requiring the contractor not to repeat the breach (“breach notice”).

(6) If, following a breach notice or a remedial notice, the contractor—

- (a) repeats the breach that was the subject of the breach notice or the remedial notice; or
- (b) otherwise breaches the agreement resulting in either a remedial notice or a further breach notice,

the Relevant Body may serve notice on the contractor terminating the agreement with effect from such date as may be specified in that notice.

(7) The Relevant Body shall not exercise its right to terminate the agreement under subparagraph (6) unless it is satisfied that the cumulative effect of the breaches is such that the Relevant Body considers that to allow the agreement to continue would be prejudicial to the efficiency of the services to be provided under the agreement.

(8) If the contractor is in breach of any obligation and a breach notice or a remedial notice in respect of that default has been given to the contractor, the Relevant Body may withhold or deduct

monies which would otherwise be payable under the agreement in respect of that obligation which is the subject of the default.

### **Termination by the Relevant Body: additional provisions specific to contracts with qualifying bodies**

**72.—**(1) Where a party to the agreement is a qualifying body, if the Relevant Body becomes aware that the qualifying body is carrying on any business which the Relevant Body considers to be detrimental to the contractor's performance of its obligations under the agreement—

- (a) the Relevant Body shall be entitled to give notice to the contractor requiring that the qualifying body ceases carrying on that business before the end of a period of not less than 28 days beginning on the day on which the notice is given ("the notice period"); and
- (b) if the contractor has not satisfied the Relevant Body that the qualifying body has ceased carrying on that business by the end of the notice period, the Relevant Body may, by a further written notice, terminate the agreement forthwith or from such date as may be specified in the notice.

(2) Where the contractor is a qualifying body and on or after the coming into force for all purposes of article 39 of the Dentists Act Order during the existence of the agreement—

- (a) the majority of the directors of the qualifying body cease to be either dental practitioners or dental care professionals;
- (b) the qualifying body has been convicted of an offence under section 43(1) of the Dentists Act(28) (directors of bodies corporate); or
- (c) the qualifying body, or a director or former director of that qualifying body, has had a financial penalty imposed on it or him by the General Dental Council pursuant to section 43B (financial penalties in relation to bodies corporate) or 44(29) (further financial penalties on bodies corporate) of the Dentists Act,

the Relevant Body may, by written notice, terminate the agreement if it considers that as a consequence the qualifying body is no longer suitable to be a contractor.

### **Agreement sanctions**

**73.—**(1) In this paragraph and paragraph 74, "agreement sanction" means—

- (a) termination of specified reciprocal obligations under the agreement;
- (b) suspension of specified reciprocal obligations under the agreement for a period of up to six months; or
- (c) withholding or deducting monies otherwise payable under the agreement.

(2) Where the Relevant Body is entitled to terminate the agreement pursuant to paragraph 68, 69, 70, 71(4), 71(6) or 72, it may instead impose any of the agreement sanctions if the Relevant Body is reasonably satisfied that the agreement sanction to be imposed is appropriate and proportionate to the circumstances which provide grounds for the Relevant Body to terminate the agreement.

(3) If the Relevant Body decides to impose an agreement sanction, it must notify the contractor of the agreement sanction that it proposes to impose, the date upon which that sanction will be imposed and provide in that notice an explanation of the effect of the imposition of that sanction.

(4) Subject to paragraph 74, the Relevant Body shall not impose the agreement sanction until at least 28 days after it has served notice on the contractor pursuant to sub-paragraph (3) unless it is satisfied that it is necessary to do so in order to—

(28) Section 43 of the Dentists Act 1984 is substituted by the Dentists Act Order 2005, article 39.

(29) Section 43B is inserted into, and section 44 is, substituted by the Dentists Act Order, article 39.

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss.

(5) Where the Relevant Body imposes an agreement sanction, it shall be entitled to charge the contractor the reasonable costs of additional administration that the Relevant Body has incurred in order to impose, or as a result of imposing, the agreement sanction.

### **Agreement sanctions and the NHS dispute resolution procedure**

74.—(1) If there is a dispute between the Relevant Body and the contractor in relation to an agreement sanction that the Relevant Body is proposing to impose, the Relevant Body shall not, subject to sub-paragraph (4), impose the proposed agreement sanction except in the circumstances specified in sub-paragraph (2).

(2) If the contractor refers the dispute relating to the agreement sanction to the NHS dispute resolution procedure within 28 days beginning on the date on which the Relevant Body served notice on the contractor in accordance with paragraph 73(3) (or such longer period as may be agreed in writing with the Relevant Body), and notifies the Relevant Body in writing that it has done so, the Relevant Body shall not impose the agreement sanction unless—

- (a) there has been a determination of the dispute pursuant to paragraph 56 and that determination permits the Relevant Body to impose the agreement sanction; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(3) If the contractor does not invoke the NHS dispute resolution procedure within the time specified in sub-paragraph (2), the Relevant Body shall be entitled to impose the agreement sanction forthwith.

(4) If the Relevant Body is satisfied that it is necessary to impose the agreement sanction before the NHS dispute resolution procedure is concluded in order to—

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

the Relevant Body shall be entitled to impose the agreement sanction forthwith, pending the outcome of that procedure.

### **Termination and the NHS dispute resolution procedure**

75.—(1) Where the Relevant Body is entitled to serve written notice on the contractor terminating the agreement pursuant to paragraph 68, 69, 70, 71(4), 71(6) or 72, it shall, in the notice served on the contractor pursuant to those provisions, specify a date on which the agreement terminates that is not less than 28 days after the date on which the Relevant Body has served that notice on the contractor unless sub-paragraph (2) applies.

(2) This sub-paragraph applies if the Relevant Body is satisfied that a period less than 28 days is necessary in order to—

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss.

(3) In a case falling with sub-paragraph (1), where—

- (a) the exceptions in sub-paragraph (2) do not apply;
- (b) the contractor invokes the NHS dispute resolution procedure before the end of the period of notice referred to in sub-paragraph (1); and
- (c) the contractor notifies the Relevant Body in writing that it has done so,

the agreement shall not terminate at the end of the notice period but instead shall only terminate in the circumstances specified in sub-paragraph (4).

(4) The agreement shall only terminate if and when—

- (a) there has been a determination of the dispute pursuant to paragraph 56 and that determination permits the Relevant Body to terminate the agreement; or
- (b) the contractor ceases to pursue the NHS dispute resolution procedure,

whichever is the sooner.

(5) If the Relevant Body is satisfied that it is necessary to terminate the agreement before the NHS dispute resolution procedure is concluded in order to—

- (a) protect the safety of the contractor's patients; or
- (b) protect itself from material financial loss,

sub-paragraphs (3) and (4) shall not apply and the Relevant Body shall be entitled to confirm, by written notice to be served on the contractor, that the agreement will nevertheless terminate at the end of the period of the notice it served pursuant to paragraph 68, 69, 70, 71(4), 71(6) or 72.

## PART 10

### MISCELLANEOUS

#### **Evidence of exemption under the Act**

76.—(1) Subject to sub-paragraph (2), the contractor shall ensure that it requests, in respect of a person who makes a declaration relating to exemption under paragraph 1(1) of Schedule 12ZA to the Act, evidence in support of that declaration.

(2) The contractor shall ensure that—

- (a) a note of the type of evidence submitted is made; or
- (b) in the case where no evidence is submitted, a note of that fact is made.

(3) Sub-paragraphs (1) and (2) do not apply where the contractor is satisfied that the person in respect of whom the declaration is made is under the age of 18 years.

#### **Clinical governance arrangements**

77.—(1) Subject to paragraph (2), the contractor shall comply with such clinical governance arrangements as the Relevant Body may establish in respect of contractors providing services under an agreement.

(2) In the case where the contractor is a Primary Care Trust, that Trust shall have effective arrangements for clinical governance in place.

(3) The contractor shall nominate a person who manages services under the agreement to have responsibility for ensuring compliance with clinical governance arrangements.

(4) In this paragraph, “clinical governance arrangements” means arrangements through which the contractor endeavours to continuously improve the quality of its services and safeguard high standards of care by creating an environment in which clinical excellence can flourish.

#### **Quality assurance system**

78.—(1) The contractor shall establish and operate a practice based quality assurance system which is applicable to all persons specified in sub-paragraph (2).



(2) The specified persons are—

- (a) any dental practitioner who performs services under the agreement; and
- (b) any other person employed or engaged by the contractor to perform or assist in the performance of services under the agreement.

(3) A contractor shall ensure that in respect of its practice based quality assurance system, it has nominated a person (who need not be connected with the contractor's practice) to be responsible for operating that system.

(4) In this paragraph, "a practice based quality assurance system" means one which comprises a system to ensure that—

- (a) effective measures of infection control are used;
- (b) all legal requirements relating to health and safety in the workplace are satisfied;
- (c) all legal requirements relating to radiological protection are satisfied; and
- (d) any requirements of the General Dental Council in respect of the continuing professional development of dental practitioners are satisfied.

#### **Insurance: negligent performance**

**79.**—(1) The contractor shall at all times hold adequate insurance against liability arising from negligent performance of clinical services under the agreement.

(2) The contractor shall not sub-contract its obligations to provide clinical services under the agreement unless it has satisfied itself that the sub-contractor holds adequate insurance against liability arising from negligent performance of such services.

(3) In this paragraph—

- (a) "insurance" means a contract of insurance or other arrangement made for the purpose of indemnifying the contractor; and
- (b) a contractor or sub-contractor shall be regarded as holding insurance if it is held by an employee of its in connection with clinical services which that employee provides under the agreement or, as the case may be, sub-contract.

#### **Public liability insurance**

**80.**—(1) The contractor shall at all times hold adequate public liability insurance in relation to liabilities to third parties arising under or in connection with the agreement which are not covered by the insurance referred to in paragraph 79(1).

(2) In this paragraph, "insurance" has the same meaning as in paragraph 79.

#### **Gifts**

**81.**—(1) The contractor shall keep a register of gifts which are given to any of the persons specified in sub-paragraph (2) by or on behalf of—

- (a) a patient;
- (b) a relative of a patient; or
- (c) any person who provides or wishes to provide services to the contractor or its patients in connection with the agreement,

and have, in its reasonable opinion, an individual value of more than £100.00.

(2) The persons referred to in sub-paragraph (1) are—

- (a) the contractor;

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- (b) where the agreement is with a qualifying body, a director, chief executive or secretary of the corporation;
  - (c) any person employed by the contractor for the purposes of the agreement;
  - (d) any dental practitioner engaged by the contractor for the purposes of the agreement;
  - (e) any spouse or civil partner of a contractor (where the contractor is an individual) or of a person specified in paragraphs (b) to (d); or
  - (f) any person whose relationship with the contractor (where the contractor is an individual) or with a person specified in paragraphs (b) to (d) has the characteristics of the relationship between husband and wife or civil partners.
- (3) Sub-paragraph (1) does not apply where—
- (a) there are reasonable grounds for believing that the gift is unconnected with services provided or to be provided by the contractor;
  - (b) the contractor is not aware of the gift; or
  - (c) in a case falling within sub-paragraph (1)(c), the contractor is not aware that the donor wishes to provide services to the contractor.
- (4) The contractor shall take reasonable steps to ensure that it is informed of gifts which fall within sub-paragraph (1) and which are given to any of the persons specified in sub-paragraph (2) (b) to (2)(f).
- (5) The register referred to in sub-paragraph (1) shall include the following information—
- (a) the name of the donor;
  - (b) in a case where the donor is a patient, the patient's National Health Service number or, if the number is not known, his address;
  - (c) in any other case, the address of the donor;
  - (d) the nature of the gift;
  - (e) the estimated value of the gift; and
  - (f) the name of the person or persons who received the gift.
- (6) The contractor shall make the register available to the Relevant Body on request.

### **Compliance with legislation and guidance**

- 82.** The contractor shall—
- (a) comply with all relevant legislation; and
  - (b) have regard to all relevant guidance issued by—
    - (i) the Relevant Body;
    - (ii) the relevant Strategic Health Authority; or
    - (iii) the Secretary of State.

### **Third party rights**

- 83.** The agreement shall not create any right enforceable by any person not a party to it.

### **Signing of documents**

- 84.—(1)** In addition to any other requirements relating to such documents whether in these Regulations or otherwise, the contractor shall ensure that the documents specified in paragraph (2) include—

- (a) the name and clinical profession of the professional who signed the document; and
  - (b) the name of the contractor on whose behalf it is signed.
- (2) The documents referred to in sub-paragraph (1) are—
- (a) forms that are required to be completed pursuant to these Regulations, where such forms require a signature;
  - (b) prescription forms; and
  - (c) any other clinical documents.