
STATUTORY INSTRUMENTS

2005 No. 3373

NATIONAL HEALTH SERVICE, ENGLAND

**The National Health Service (Personal Dental
Services Agreements) Regulations 2005**

<i>Made</i>	- - - -	<i>7th December 2005</i>
<i>Laid before Parliament</i>		<i>9th December 2005</i>
<i>Coming into force</i>	- -	<i>1st January 2006</i>

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred upon her by sections 28D, 28E and 126(4) of the National Health Service Act 1977⁽¹⁾ and section 4(5) of the National Health Service and Community Care Act 1990⁽²⁾.

PART 1

GENERAL

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Personal Dental Services Agreements) Regulations 2005 and shall come into force on 1st January 2006.

(2) These Regulations apply in relation to England only⁽³⁾.

(1) 1977 c. 49; section 28D was inserted by section 21(1) of the National Health Service (Primary Care) Act 1997 (c. 46) (“the 1997 Act”); and is amended by the Health Act 1999 (c. 8) (“the 1999 Act”), section 65(1) and Schedule 4, paragraphs 4 and 16(a); the National Health Service Reform and Health Care Professions Act 2002 (c. 17) (“the 2002 Act”), section 4(3), Schedule 3, paragraph 7(3); and the Health and Social Care (Community Health and Standards) Act 2003 (c. 43) (“the 2003 Act”), section 177(1) to (6) and section 184 and Schedule 11, paragraph 15. Section 28E is inserted by section 22(1) of the 1997 Act; and amended by the 1999 Act, section 65(2) and Schedule 5; the Health and Social Care Act 2001 (c. 15) (“the 2001 Act”), section 27(5)(a); the 2002 Act, section 4(3) and Schedule 3, paragraph 8; and the 2003 Act, section 177(7) to (11). Section 126(4) is amended by the National Health Service and Community Care Act 1990 (c. 19) (“the 1990 Act”), section 65(2); the 1999 Act, Schedule 4, paragraph 37(6); and the 2001 Act, Schedule 5, paragraph 5(13)(b). *See* section 128(1) of the Act as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of “prescribed” and “regulations”.

(2) 1990 c. 19.

(3) As regards Wales, the functions of the Secretary of State under sections 28D, 28E and 126(4) of the Act and section 4 of the 1990 Act were transferred to Wales under S.I. 1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(5) and as read with section 40(1) of the 2002 Act and section 197(1) of the 2003 Act.

Interpretation

2.—(1) In these Regulations—

“the Act” means the National Health Service Act 1977;

“the 1990 Act” means the National Health Service and Community Care Act 1990;

“additional services” means one or more of—

- (a) advanced mandatory services;
- (b) dental public health services;
- (c) domiciliary services;
- (d) orthodontic services; and
- (e) sedation services;

“adjudicator” means the Secretary of State or a person or persons appointed by the Secretary of State under section 4(5) of the 1990 Act (NHS contracts) or paragraph 55(4) of Schedule 3 (NHS dispute resolution procedure);

“advanced mandatory services” means any primary dental service that would fall within the services described in regulation 14 of the GDS Contracts Regulations, but by virtue of the high level of facilities, experience or expertise required in respect of a particular patient, is provided as a referral service;

“agreement” means, except where the context otherwise requires, an agreement for primary dental services made under section 28C of the Act;

“Band 1 course of treatment” means a course of treatment, including a course of treatment consisting of urgent treatment, provided to a patient in respect of which a Band 1 NHS Charge is payable pursuant to the NHS Charges Regulations, or would be payable if the patient was not an exempt person;

“Band 2 course of treatment” means a course of treatment provided to a patient in respect of which a Band 2 NHS Charge is payable pursuant to the NHS Charges Regulations, or would be payable if the patient was not an exempt person;

“Band 3 course of treatment” means a course of treatment provided to a patient in respect of which a Band 3 NHS Charge is payable pursuant to the NHS Charges Regulations, or would be payable if the patient was not an exempt person;

“banded course of treatment” means a Band 1, Band 2 or Band 3 course of treatment;

“bank holiday” means any day that is specified or proclaimed as a bank holiday in England pursuant to section 1 of the Banking and Financial Dealings Act 1971(4);

“bridge” means a fixed or removable bridge which takes the place of any teeth;

“case assessment”, in respect of an orthodontic course of treatment, means a clinical examination of the patient, including the taking of such radiographs, colour photographs and models as are required in order to determine what orthodontic treatment (if any) is to be provided to the patient;

“charge exempt course of treatment” means a course of treatment that involves the examination and assessment of a patient leading to—

- (a) the issue of a prescription;
- (b) the repair of a dental appliance;
- (c) the arrest of bleeding; or
- (d) the removal of sutures,

(4) 1971 c. 80.

which, by virtue of regulation 3(2)(d) or (e) of the NHS Charges Regulations, is provided free of charge to the patient;

“charity trustee” means one of the persons having the general control and management of the administration of a charity;

“child” means a person who has not attained the age of 16 years;

“complete”, in relation to—

- (a) a course of treatment, means that—
 - (i) where no treatment plan has to be provided in respect of a course of treatment pursuant to paragraph 8(5) of Schedule 3 (treatment plans), all the treatment recommended to, and agreed with, the patient by the contractor at the initial examination and assessment of that patient has been provided to the patient; or
 - (ii) where a treatment plan has to be provided to the patient pursuant to paragraph 8(1) of Schedule 3, all the treatment specified on that plan by the contractor (or that plan as revised in accordance with paragraph 8(3) of that Schedule) has been provided to the patient; and
- (b) an orthodontic course of treatment, means that—
 - (i) where the contractor determines in accordance with paragraph 4 of Schedule 1 (patients to whom orthodontic treatment may be provided) that no orthodontic treatment should be provided following the case assessment, the completion of the case assessment; or
 - (ii) where the contractor has determined that orthodontic treatment should be provided following the case assessment, all of the orthodontic treatment specified on the orthodontic treatment plan by the contractor pursuant to paragraph 6 of Schedule 1 (orthodontic treatment plans) (or that plan as revised in accordance with paragraph 6(3) of that Schedule) has been provided to the patient,

and “completed” shall be construed accordingly;

“contractor” means, except where the context otherwise requires—

- (a) where a Primary Care Trust is not providing services under the agreement, a person or persons other than a Primary Care Trust, who is a party, or are parties, to the agreement; or
- (b) where a Primary Care Trust is providing services under the agreement, that Primary Care Trust and any other person or persons (other than a Strategic Health Authority) who is a party, or are parties, to the agreement;

“course of treatment” means—

- (a) an examination of a patient, an assessment of his oral health, and the planning of any treatment to be provided to that patient as a result of that examination and assessment; and
- (b) the provision of any planned treatment (including any treatment planned at a time other than the time of the initial examination) to that patient,

provided by, except where expressly provided otherwise, one or more providers of primary dental services, but it does not include the provision of any orthodontic services or dental public health services;

“dental appliance” means a denture or bridge and for the purposes of this definition, a denture includes an obturator;

“dental care professional” means a person whose name is included in the register of dental care professionals or on the appropriate roll for dental auxiliaries established in accordance with Part II of the Dental Auxiliaries Regulations 1986⁽⁵⁾;

“dental performers list” means a list of dental practitioners prepared in accordance with regulations made under section 28X of the Act⁽⁶⁾ (persons performing primary medical and dental services);

“dental public health services” means services provided by the contractor by virtue of section 16CB(4)(c) of the Act⁽⁷⁾ (dental public health);

“Dentists Act” means the Dentists Act 1984⁽⁸⁾;

“Dentists Act Order” means the Dentists Act 1984 (Amendment) Order 2005⁽⁹⁾;

“Dentists Register” means the register maintained by the General Dental Council pursuant to section 14 of the Dentists Act⁽¹⁰⁾ (the dentists register and the registrar);

“domiciliary services” means a course of treatment, or part of a course of treatment, provided at a location other than—

- (a) the practice premises of any provider of primary dental services;
- (b) a mobile surgery of any provider of primary dental services; or
- (c) a prison;

“exempt person” means a person who is, by virtue of either Schedule 12ZA to the Act⁽¹¹⁾ (dental charging: exemptions) or the NHS Charges Regulations, exempt from the need to pay an NHS Charge in respect of the services he has received under the agreement;

“family member” means—

- (a) a spouse;
- (b) a civil partner;
- (c) a person whose relationship with the registered patient has the characteristics of the relationship between husband and wife, or civil partners;
- (d) a parent or step-parent;
- (e) a son;
- (f) a daughter;
- (g) a child of whom the person is—
 - (i) the guardian; or
 - (ii) the carer duly authorised by the local authority to whose care the child has been committed under the Children Act 1989⁽¹²⁾; or
- (h) a grandparent;

“FHSAA” means the Family Health Services Appeal Authority constituted under section 49S of the Act⁽¹³⁾ (the Family Health Services Appeal Authority);

“financial year” means the period of 12 months ending with 31st March in any year;

(5) [S.I. 1986/887](#); relevant amending instrument is [S.I. 2002/1671](#).

(6) Section 28X was inserted into the Act by section 179(1) of the 2003 Act.

(7) Section 16CB was inserted into the Act by section 171(1) of the 2003 Act.

(8) [1984 \(c. 24\)](#) amended by section 41(1) of, and Schedule 2 paragraph 62 to, the 1997 Act, sections 31 and 37 of, and Schedule 9 to, the 2002 Act, section 187 of, and Schedule 12 to, the 2003 Act and [S.I. 1987/2047](#), [1991/1705](#), [1996/1496](#), [1998/811](#) and [2840](#), [2001/3926](#), [2002/3135](#), [2003/833](#), [2004/1947](#) and [2005/2011](#).

(9) [S.I. 2005/2011](#).

(10) Section 14 of the Dentists Act 1984 is prospectively substituted by the Dentists Act Order, article 6.

(11) Schedule 12ZA was inserted into the Act by section 183(2) of the 2003 Act.

(12) [1989 c. 41](#).

(13) Section 49S was inserted into the Act by section 27(1) of the 2001 Act.

“GDS Contracts Regulations” means the National Health Service (General Dental Services Contracts) Regulations 2005(14);

“health care professional” has the same meaning as in section 28M of the Act(15) (persons eligible to enter into GDS contracts) and “health care profession” shall be construed accordingly;

“health service body” has, unless the context otherwise requires, the meaning given to it in section 4(2) of the 1990 Act(16) (NHS contracts);

“licensing body” means any body that licenses or regulates any profession;

“listed”, in relation to drugs, medicines or appliances, means such drugs, medicines or appliances as are included in a list for the time being approved by the Secretary of State for the purposes of section 41(1)(c) of the Act(17) (arrangements for pharmaceutical services);

“mandatory services” means the services described in regulation 14 of the GDS Contracts Regulations;

“mobile surgery”, except where expressly provided otherwise in these Regulations, means any vehicle in which services under the agreement are to be provided;

“national disqualification” means—

- (a) a decision made by the FHSAA under section 49N or under regulations corresponding to that section made under section 28X(4) of the Act(18) (national disqualifications);
- (b) a decision under provisions in force in Scotland or Northern Ireland corresponding to section 49N of the Act; or
- (c) a decision by the NHS Tribunal which is treated as a national disqualification by the FHSAA by virtue of regulation 6(4)(b) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001(19) or regulation 6(4)(b) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002(20);

“NHS Charge” means a charge made to the patient for provision of services pursuant to the NHS Charges Regulations;

“NHS Charges Regulations” means the National Health Service (Dental Charges) Regulations 2005(21);

“NHS contract” has the meaning assigned to it in section 4 of the 1990 Act;

“NHS dispute resolution procedure” means the procedure for disputes specified in paragraphs 55 and 56 of Schedule 3;

“NHS Tribunal” means the Tribunal constituted under section 46 of the Act(22) for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14th December 2001 and in relation to Wales only until 26th August 2002(23);

(14) S.I. 2005/ .

(15) Section 28M was inserted into the Act by section 172(1) of the 2003 Act.

(16) Section 4(2) was amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 68, the Health Act 1999 (c. 8), Schedule 4, paragraph 76(a) and Schedule 5, the 2002 Act, Schedule 1, paragraph 40 and Schedule 5, paragraph 31.

(17) Section 41 of the Act was substituted by the 2001 Act, section 42(1) and amended by the 2002 Act, section 2(5) and Schedule 3, paragraphs 1 and 13, by the 2003 Act, section 184 and Schedule 11, paragraphs 7 and 18(1), (2) and (3) and by S.I. 2003/1590, article 3 and the Schedule, paragraph 3.

(18) Section 49N was inserted into the Act by section 25 of the 2001 Act. Section 28X was inserted by section 179 of the 2003 Act.

(19) S.I. 2001/3744 amended by S.I. 2002/2469.

(20) S.I. 2002/1920.

(21) S.I. 2005/ .

(22) Section 46 was revoked by the 2001 Act, section 67, Schedule 5, paragraph 5 and Schedule 6, Part 1.

(23) See S.I. 2001/3738, article 2(5) and (6)(b), which sets out the prescribed cases for England and S.I. 2002/1919, article 2(2) and (3)(b), which sets out the prescribed cases for Wales.

“normal surgery hours” means the times at which the contractor has agreed with the Relevant Body (and specified in the agreement) that the surgery will be open to patients for the provision of services;

“NPSA” means the National Patient Safety Agency established as a Special Health Authority by the National Patient Safety Agency (Establishment and Constitution) Order 2001⁽²⁴⁾;

“orthodontic appliance” means a device used in the mouth to move or immobilise the teeth in order to correct or prevent malocclusion;

“orthodontic course of treatment” means—

- (a) a case assessment of a patient; and
- (b) the provision of any orthodontic treatment that the contractor determines should be provided to the patient in accordance with Part 2 of Schedule 1 (orthodontic services);

“orthodontic services” means the provision of orthodontic courses of treatment or the services referred to in paragraph 5(2) of Schedule 1 (repairs);

“orthodontic treatment” means treatment of, or treatment to prevent, malocclusion of the teeth and jaws, and irregularities of the teeth;

“parent”, in relation to any child, means a parent or other person who has parental responsibility for that child;

“patient” means, unless the context otherwise requires, a person to whom the contractor is providing services under the agreement;

“patient record” means a form supplied by a Relevant Body for the purpose of maintaining a record of treatment, and may include an electronic form;

“practice premises”, except where expressly provided otherwise in these Regulations, means an address specified in the agreement as one at which services are to be provided under the agreement but does not include a mobile surgery;

“prescriber” means a dental practitioner who is either engaged or employed by the contractor or is a party to the agreement;

“primary care list” means—

- (a) a list of persons performing primary medical or dental services under section 28X of the Act⁽²⁵⁾;
- (b) a list of persons undertaking to provide general ophthalmic services or, as the case may be, pharmaceutical services prepared in accordance with regulations made under section 39, 42 or 43 of the Act⁽²⁶⁾;
- (c) a list of persons approved for the purposes of assisting in the provision of any services mentioned in paragraph (b) or (d) prepared in accordance with regulations made under section 43D of the Act⁽²⁷⁾;

(24) [S.I.2001/1743](#).

(25) Section 28X was inserted into the Act by section 179(1) of the 2003 Act.

(26) Section 39 is amended by sections 1 and 2 of, paragraph 52 of Schedule 1 to, the Health Services Act 1980 ([c. 53](#)); sections 1 and 24 of, Schedule 9 to, the Health and Social Security Act 1984 ([c. 48](#)); section 9 of the 1999 Act; section 20 of the 2001 Act; and section 2 of, paragraphs 1 and 12 of Schedule 2 to, the 2002 Act. Section 42 is amended by section 3 of the National Health Service (Amendment) Act 1986 ([c. 66](#)); section 2 of, paragraph 30 of Schedule 1 to, the Health Authorities Act 1995 ([c. 17](#)); sections 20, 23, 43 and 67 of, Schedule 6 to, the 2001 Act; and section 2 of, paragraphs 1 and 16 of Schedule 2 to, the 2002 Act. Section 43 is amended by section 21 to the Health Services Act 1980; section 66 of, paragraph 18 of Schedule 9 to, the 1990 Act; section 2 of, paragraph 31 of Schedule 1 to, the Health Authorities Act 1995; sections 29 and 41 of, paragraph 14 of Schedule 2 to, the 1997 Act; section 1 of, paragraph 6 of Schedule 1 to, the Pharmacists (Fitness to Practice) Act 1997 ([c. 19](#)); section 20 of the 2001 Act; sections 2 and 42 of, paragraphs 1 and 17 of Schedule 2 to, the 2002 Act; and section 184 of, paragraphs 7 and 19 of Schedule 11 to, the 2003 Act.

(27) Section 43D was inserted into the Act by section 24 of the 2001 Act.

- (d) a list of persons who undertook to provide general medical services or general dental services prepared in accordance with regulations made under sections 29 or 35 of the Act⁽²⁸⁾;
- (e) a services list which fell within the meaning of section 8ZA of the National Health Service (Primary Care) Act 1997⁽²⁹⁾;
- (f) a list corresponding to a services list prepared by virtue of regulations made under section 41 of the Health and Social Care Act 2001⁽³⁰⁾; or
- (g) a list corresponding to any of the above lists in Scotland or Northern Ireland;

“Primary Care Trust” means, except where the context otherwise requires, the Primary Care Trust which is a party, or prospective party, to an agreement;

“prison” includes a young offender institution but not a secure training centre or a naval, military or air force prison, and for the purposes of this definition—

- (a) “secure training centre” means a place in which offenders subject to detention and training orders under section 100 of the Powers of Criminal Courts (Sentencing) Act 2000⁽³¹⁾ (offenders under 18: detention and training orders) may be detained and given training and education and prepared for their release; and
- (b) “young offender institution” means a place for the detention of offenders sentenced to detention in a young offender institution or to detention in a young offender institution as part of a longer custodial sentence, including custody for life;

“private”, in the context of services or treatment, means otherwise than under the agreement or Part 1 of the Act, and “privately” shall be construed accordingly;

“professional registration number” means the number against a dental practitioner’s name in the Dentists Register;

“referral notice” means the notice referred to in paragraph 10(2)(a) of Schedule 3 (referral to another contractor, a hospital or other relevant service provider for advanced mandatory, domiciliary or sedation services);

“referral service” means one or more of advanced mandatory services, domiciliary services or sedation services provided by the contractor to a patient who has, during a course of treatment, been referred to the contractor by—

- (a) another contractor; or
 - (b) another provider of primary dental services under Part 1 of the Act,
- for the provision of one or more of those services as part of that course of treatment;

“referral treatment plan” means a treatment plan provided pursuant to paragraph 2(1) of Schedule 1 or that plan as varied in accordance with paragraph 2(2) of that Schedule;

“register of dental care professionals” means the register maintained by the General Dental Council under section 36B of the Dentists Act⁽³²⁾ (the dental care professionals register);

“Relevant Body” means—

- (a) in a case where a contractor is a party to an agreement with a Primary Care Trust, that Primary Care Trust; and

(28) Sections 29 and 36 were repealed by sections 175(2) and 196 of, and Schedule 14 Part 4 to, the 2003 Act.

(29) 1997 c. 46. Section 8ZA was inserted into this Act by section 26(2) of the Health and Social Care Act 2001 and repealed by section 196 and Schedule 14 Part 4 to the 2003 Act.

(30) 2001 c. 15.

(31) 2000 c. 6.

(32) Section 36B is prospectively inserted into the Dentists Act 1984 by article 29 of the Dentists Act Order.

- (b) in a case where a contractor is a party to an agreement with a Strategic Health Authority, that Strategic Health Authority;

“relevant Strategic Health Authority” means the Strategic Health Authority established for an area which includes the area for which the Primary Care Trust is established;

“sedation services” means a course of treatment provided to a patient during which the contractor administers one or more drugs to a patient, which produce a state of depression of the central nervous system to enable treatment to be carried out, and during and in respect of that period of sedation—

- (a) the drugs and techniques used to provide the sedation are deployed by the contractor in a manner that ensures loss of consciousness is rendered unlikely; and
- (b) verbal contact with the patient is maintained in so far as is reasonably possible;

“trauma” means damage to teeth, gingival tissues or alveoli caused by a force arising outside the mouth, resulting in mobility, luxation, subluxation or fracture of the hard tissues or injury to the soft tissues;

“unit of dental activity” means the unit of activity which is in the agreement used to—

- (a) express the amount of; and
- (b) measure in accordance with Part 1 of Schedule 2 the provision of, mandatory services and advanced mandatory services provided under the agreement;

“unit of orthodontic activity” means the unit of activity which is in the agreement used to—

- (a) express the amount of; and
- (b) measure in accordance with Part 2 of Schedule 2 the provision of, orthodontic services provided under the agreement;

“urgent treatment” means a course of treatment that consists of one or more of the treatments listed in Schedule 4 to the NHS Charges Regulations (urgent treatment under Band 1 charge) that are provided to a person in circumstances where—

- (a) a prompt course of treatment is provided because, in the opinion of the contractor, that person’s oral health is likely to deteriorate significantly, or the person is in severe pain by reason of his oral condition; and
- (b) treatment is provided only to the extent that is necessary to prevent that significant deterioration or address that severe pain; and

“working day” means any day apart from Saturday, Sunday, Christmas Day, Good Friday or a bank holiday.

(2) In these Regulations—

- (a) the use of the term it in relation to the contractor shall be deemed to include a reference to a contractor that is an individual dental practitioner or two or more persons contracting together to provide services under an agreement and related expressions shall be construed accordingly; and
- (b) references to forms supplied by the Primary Care Trust to contractors includes electronic forms and forms which are generated electronically, but does not include prescription forms.

PART 2

CONTRACTORS

Conditions: introductory

3. A Relevant Body may only enter into an agreement if the conditions set out in—
- (a) regulation 4; and
 - (b) in the case of an agreement to be entered into with a qualifying body⁽³³⁾, on or after the coming into force for all purposes of article 39 of the Dentists Act Order (substitution of sections 43 and 44), regulation 5,

are met.

General conditions relating to all agreements

4.—(1) A Relevant Body may make an agreement with an individual falling within section 28D(1)(b) to (d) if that individual does not fall within paragraph (3).

- (2) A Relevant Body may make an agreement with a qualifying body only if—

- (a) the qualifying body; or
- (b) any director, chief executive or secretary of the qualifying body,

does not fall within paragraph (3).

- (3) A person falls within this paragraph if—

- (a) he or it (in the case of a qualifying body) is the subject of a national disqualification;
- (b) subject to paragraph (4), he or it is disqualified or suspended (other than by an interim suspension order or direction pending an investigation) from practising by any licensing body anywhere in the world;
- (c) within the period of five years prior to the date the agreement is to be commenced or, if earlier, the date on which the agreement is to be signed—
 - (i) he has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body, unless he has subsequently been employed by that health service body or another health service body and paragraph (5) applies to him or that dismissal was the subject of a finding of unfair dismissal by any competent tribunal or court; or
 - (ii) he or it has been 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⁽³⁴⁾ respectively) unless his or its name has subsequently been included in such a list;
- (d) 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;
- (e) subject to paragraph (6), he has been convicted outside the United Kingdom of an offence—

⁽³³⁾ A “qualifying body” is defined in section 28D(2) of the Act.

⁽³⁴⁾ Section 49F was inserted into the Act by section 25 of the 2001 Act and amended by the 2002 Act, Schedule 2, paragraph 21 and the 2003 Act, Schedule 14, Part 2.

- (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;
 - (f) he has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933⁽³⁵⁾ (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⁽³⁶⁾ (offences against children under the age of 17 years to which special provisions apply) committed on or after 1st April 2006;
 - (g) 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;
 - (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986⁽³⁷⁾ unless that order has ceased to have effect or has been annulled; or
 - (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;
 - (h) an administrator, administrative receiver or receiver is appointed in respect of it;
 - (i) he has within the period of five years prior to the date the agreement is to be commenced or, if earlier, the date on which the agreement is to be signed—
 - (i) been 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;
 - (ii) been removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990⁽³⁸⁾ (powers of the Court of Session to deal with management of charities), from being concerned in the management or control of any body; or
 - (iii) been subject to a disqualification order under the Company Directors Disqualification Act 1986⁽³⁹⁾, the Companies (Northern Ireland) Order 1986⁽⁴⁰⁾ or to an order made under section 429(2)(b) of the Insolvency Act 1986⁽⁴¹⁾ (failure to pay under county court administration order).
- (4) A person shall not fall within paragraph (3)(b) where the Relevant Body is satisfied that the disqualification or suspension from practising is imposed by a licensing body outside the United Kingdom and it does not make the person unsuitable to be—
- (a) a party to an agreement; or
 - (b) in the case of an agreement with a qualifying body, a director, chief executive or secretary of the qualifying body,

as the case may be.

⁽³⁵⁾ 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; and modified by the Criminal Justice Act 1988, section 170(1), Schedule 15, paragraph 9.

⁽³⁶⁾ 1995 c. 46.

⁽³⁷⁾ 1986 c. 45. Schedule 4A was inserted by section 257 of, and Schedule 20 to, the Enterprise Act 2002 (c. 40).

⁽³⁸⁾ 1990 c. 40.

⁽³⁹⁾ 1986 c. 46 as amended by the Insolvency Act 2000 (c. 39).

⁽⁴⁰⁾ S.I. 1986/1032 (N.I.6).

⁽⁴¹⁾ 1986 c. 45.

(5) Where a person has been employed as a member of a health care profession any subsequent employment must also be as a member of that profession.

(6) A person shall not fall within paragraph (3)(e) where the Relevant Body is satisfied that the conviction does not make the person unsuitable to be—

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

Additional conditions relating to agreements with qualifying bodies

5.—(1) Subject to paragraph (2), it is a condition in the case of an agreement to be entered into with a qualifying body on or after the date of the coming into force of article 39 of the Dentists Act Order, that no—

- (a) offence has been or is being committed under section 43 of the Dentists Act; or
- (b) financial penalty has been imposed under section 43B or 44 of the Dentists Act.

(2) Paragraph (1) shall not apply if the Relevant Body is satisfied that any offence under section 43 or penalty imposed under section 43B or 44 of the Dentists Act does not make the qualifying body unsuitable to be a contractor, whether by virtue of the time that has elapsed since any conviction or penalty was imposed, or otherwise.

Reasons

6.—(1) Where a Relevant Body is of the view that the conditions in regulation 4 or 5 for entering into an agreement are not met it shall notify in writing the person or persons intending to enter into the agreement of its view and its reasons for that view and of his, its, or their right of appeal under regulation 7.

(2) The Relevant Body shall also notify in writing of its view and its reasons for that view, any director, chief executive or secretary of a qualifying body that is notified under paragraph (1) where its reasons for the decision relate to that person or those persons.

Appeal

7. A person who has been served with a notice under regulation 6(1) may appeal to the FHSAA against the decision of the Relevant Body that the conditions in regulation 4 or 5 are not met by giving notice in writing to the FHSAA within the period of 28 days beginning on the day that the Relevant Body served its notice.

PART 3

PRE-AGREEMENT DISPUTE RESOLUTION

Pre-agreement disputes

8.—(1) Subject to paragraphs (2) and (3), if in the course of negotiations intending to lead to an agreement the prospective parties to that agreement are unable to agree on a particular term of the agreement, either party may, subject to paragraph (2), refer the dispute to the Secretary of State to consider and determine the matter.

(2) Both parties to the prospective agreement must make every reasonable effort to communicate and co-operate with each other with a view to resolving a dispute arising during the course of negotiations, before referring the dispute for determination under paragraph (1).

(3) Disputes referred to the Secretary of State in accordance with paragraph (1), or section 4(4) of the 1990 Act, shall be considered and determined in accordance with the provisions of paragraphs 55(4) to 55(13) and 56(1) of Schedule 3, and paragraph (4) (where it applies) of this regulation.

(4) In the case of a dispute referred to the Secretary of State under paragraph (1), the determination—

- (a) may specify terms to be included in the proposed agreement;
- (b) may require the Relevant Body to proceed with the proposed agreement, but may not require the proposed contractor to proceed with the proposed agreement; and
- (c) shall be binding upon the prospective parties to the agreement.

PART 4

HEALTH SERVICE BODY STATUS

Health service body status

9.—(1) A contractor shall be regarded as a health service body for the purposes of section 4 of the 1990 Act from the date it makes an agreement unless—

- (a) in the case of an agreement with a single individual or qualifying body, that individual or body; or
- (b) in the case of any other agreement, the proposed parties to the agreement (other than the Relevant Body),

object in a written notice served on the Relevant Body at any time prior to the agreement being made.

(2) Where a contractor is to be regarded as a health service body for the purposes of section 4 of the 1990 Act pursuant to paragraph (1), any change in the parties comprising the contractor shall not affect the health service body status of the contractor.

(3) If, pursuant to paragraph (1) or (4), a contractor is to be regarded as a health service body, that fact shall not affect the nature of, or any rights or liabilities arising under, any other agreement or contract with a health service body entered into by that contractor before the date on which the contractor is to be so regarded.

(4) A contractor may at any time request a variation of the agreement to include or remove provision from the agreement that the agreement is an NHS contract, and if it does so—

- (a) the Relevant Body shall agree to the variation; and
- (b) the procedure in paragraph 60(1) of Schedule 3 (variation of a contract: general) shall apply.

(5) Where, pursuant to paragraph (4), the Relevant Body agrees to a variation of the agreement, the contractor shall—

- (a) be regarded; or
- (b) subject to paragraph (7), cease to be regarded,

as a health service body for the purposes of section 4 of the 1990 Act from the date that variation takes effect pursuant to paragraph 60(1) of Schedule 3.

(6) Subject to paragraph (7), a party or parties who were to be regarded as a health service body pursuant to paragraphs (1) or (4), as the case may be, shall cease to be a health service body for the purposes of section 4 of the 1990 Act if the agreement is terminated.

(7) Where a contractor ceases to be a health service body pursuant to—

- (a) paragraph (5) or (6), it shall continue to be regarded as a health service body for the purposes of being a party to any other NHS contract entered into after it became a health service body but before the date on which the contractor ceased to be a health service body (for which purposes it ceases to be such a body on the termination of that NHS contract);
- (b) paragraph (5), it shall, if it or the Relevant Body has referred any matter to the NHS dispute resolution procedure before it ceases to be a health service body, be bound by the determination of the adjudicator as if the dispute had been referred pursuant to paragraph 54 of Schedule 3 (dispute resolution: non-NHS contracts);
- (c) paragraph (6), it shall continue to be regarded as a health service body for the purposes of the NHS dispute resolution procedure where that procedure has been commenced—
 - (i) before the termination of the agreement; or
 - (ii) after the termination of the agreement, whether in connection with, or arising out of, the termination of the agreement or otherwise,for which purposes it ceases to be such a body on the conclusion of that procedure.

PART 5

AGREEMENTS: REQUIRED TERMS

NHS contracts

10. If the contractor is to be regarded as a health service body, the agreement must state that it is an NHS contract.

Additional services

11. If the agreement includes the provision of additional services, it must contain in relation to each such service as is included in the agreement, terms that have the same effect as those specified in Schedule 1 in so far as they are relevant to that service.

Agreements: general

12.—(1) An agreement must specify—

- (a) the services to be provided by the contractor;
- (b) the duration of the agreement;
- (c) to whom such services are to be provided; and
- (d) the postal address of each of the premises to be used by the contractor or any sub-contractor for the provision of such services, or, if the contractor is to provide services from a mobile surgery, that fact.

(2) The premises referred to in paragraph (1)(d) do not include any place in which a patient is residing.

Units of dental activity

13.—(1) Where an agreement includes the provision of mandatory or advanced mandatory services, the agreement must specify the number of units of dental activity to be provided by the contractor—

- (a) where the agreement begins on 1st April, in each financial year or, by virtue of the duration of the agreement, part financial year; or

- (b) where the agreement begins on a date other than 1st April, in the remainder of the financial year in which the agreement begins, and in each financial year thereafter.

(2) An agreement must contain terms which have the effect of those specified in Part 1 of Schedule 2 in relation to the calculation of the number of units of dental activity that the contractor has provided under the agreement.

Units of orthodontic activity

14.—(1) Where an agreement includes the provision of orthodontic services, the agreement must specify the number of units of orthodontic activity to be provided by the contractor—

- (a) where the agreement begins on 1st April, in each financial year or, by virtue of the duration of the agreement, part financial year; or
- (b) where the agreement begins on a date other than 1st April, in the remainder of the financial year in which the agreement begins, and in each financial year or part financial year thereafter.

(2) Where paragraph (1) applies, the agreement must also contain terms which have the effect of those specified in Part 2 of Schedule 2 in relation to the calculation of how many units of orthodontic activity a contractor has provided under the agreement.

Under-provision of units of dental activity or units of orthodontic activity

15.—(1) The agreement shall provide that the Relevant Body shall not, pursuant to Part 9 of Schedule 3 (variation and termination of agreements), be entitled to take any action for breach of a term of the agreement giving effect to regulation 13 or 14 (including termination of the agreement) where paragraph (2) applies.

(2) Subject to paragraph (4), this paragraph applies where the contractor has failed to provide—

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

it is contracted to provide pursuant to a term of the agreement giving effect to regulation 13 or 14 where—

- (i) 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; and
- (ii) the contractor agrees to provide and does so provide the units it has failed to provide within such period as the Relevant Body specifies in writing, such period to consist of not less than 60 days.

(3) Paragraphs (1) and (2) shall not prevent the Relevant Body from taking action under Part 9 of Schedule 3 for breach of contract (including terminating the agreement) on other grounds.

(4) In the case of an agreement with a duration period of less than 12 months, the period of 60 days in paragraph (2)(ii) may not apply if the Relevant Body considers it not appropriate or considers that another period of less than 60 days should apply.

Domiciliary services and sedation services

16. Where an agreement includes the provision of domiciliary services or sedation services, the agreement must specify the number of courses of treatment that the contractor is—

- (a) to provide; or
- (b) to contribute to where provided as a referral service,

that involve the provision of domiciliary services or sedation services—

- (i) where the contract begins on 1st April, in each financial year; or
- (ii) where the contract begins on a date other than 1st April, in the remainder of the financial year in which the contract begins, and in each financial year thereafter for which the contract continues.

Finance

17.—(1) The agreement must contain a term which has the effect of requiring—

- (a) the Relevant Body to make payments to the contractor under the agreement promptly and in accordance with both the terms of the agreement and any other conditions relating to the payment contained in directions given by the Secretary of State under section 28E(3A) of the Act⁽⁴²⁾ (personal medical or dental services: regulations);
- (b) the contractor to make payments promptly to the Relevant Body and in accordance with both the terms of the agreement and any other conditions relating to the payment contained in directions given by the Secretary of State under section 17 (Secretary of State's directions: exercise of functions) or 28E(3A) of the Act.

(2) The obligation referred to in paragraph (1) is subject to any right the Relevant Body has to set off against an amount payable to the contractor an amount that—

- (a) is owed by the contractor to the Relevant Body under the agreement;
- (b) has been paid to the contractor owing to an error or in circumstances when it was not due; or
- (c) the Relevant Body may withhold from the contractor in accordance with the terms of the agreement or any other applicable provisions contained in directions given by the Secretary of State under section 28E(3A).

(3) The agreement must contain a term to the effect that where, pursuant to directions under section 17 or 28E(3A) of the Act, a Relevant Body is required to make a payment to a contractor under an agreement but subject to conditions, those conditions are to be a term of the agreement.

Fees, charges and financial interests of the contractor

18.—(1) The agreement must contain terms relating to fees, charges and financial interests which have the same effect as those set out in paragraphs (2) to (4).

(2) The contractor shall not, either itself or through any other person, demand or accept a fee or other remuneration for its own or another's benefit from—

- (a) any patient of its for the provision of any treatment under the agreement, except as otherwise provided in the NHS Charges Regulations; or
- (b) any person who has requested services under the agreement for himself or a family member, as a prerequisite to providing services under the agreement to that person or his family member.

(3) The agreement must contain a term that—

- (a) only permits the contractor to collect from any patient of its any charge that that patient is required to pay by virtue of the NHS Charges Regulations, in accordance with the requirements of those Regulations; and
- (b) provides for obligations imposed on the contractor by virtue of the NHS Charges Regulations to be terms of the agreement.

⁽⁴²⁾ Section 17 of the Act was substituted by the Health Act 1999 (c. 8), section 12(1), and amended by the 2001 Act, section 67(1) and Schedule 5, paragraph 5(1) and (3) and the 2002 Act, section 1(3) and Schedule 1, paragraph 7. Section 28E(3A) was inserted by section 177(8) of the 2003 Act.

- (4) The agreement must contain a term that requires the contractor in making a decision—
- (a) as to what services to recommend or provide to a patient who has sought services under the agreement; or
 - (b) to refer a patient for other services by another contractor, hospital or other relevant service provider under Part 1 of the Act,

to do so without regard to its own financial interests.

(5) The term “patient” in paragraph (3) shall have the same meaning as in regulation 2(1) of the NHS Charges Regulations.

Arrangements on termination

19. An agreement shall make suitable provision for arrangements on termination of an agreement including the consequences (whether financial or otherwise) of the agreement ending.

Other contractual terms

20.—(1) An agreement must, unless it is of a type or nature to which a particular provision does not apply, contain other terms which have the same effect as those specified in Schedule 3 except paragraphs 55(4) to 55(13) and 56 and Schedule 5.

(2) The paragraphs specified in paragraph (1) shall have effect in relation to the matters set out in those paragraphs.

(3) Where an agreement does not commence on 1st April in any financial year or the duration of an agreement is less than 12 months, there must be a contractual term—

- (a) specifying the date and periods for the purposes of a mid-year review of the services provided; and
- (b) which, other than as to the date and periods, have similar effect as those specified in paragraphs 58(3) to (8) and 59 of Schedule 3 in respect of the requirement and procedure for carrying out mid-year reviews.

PART 6

RIGHT TO A GENERAL DENTAL SERVICES CONTRACT

Right to a general dental services contract

21.—(1) A contractor which is providing mandatory services and which wishes a general dental services contract to be entered into pursuant to this regulation shall notify the Relevant Body in writing at least three months before the date on which it wishes the general dental services contract to be entered into.

(2) A notice under paragraph (1) shall—

- (a) state that the contractor wishes to terminate the agreement and the date on which the contractor wishes the agreement to terminate which must be at least three months after the date of service of the notice;
- (b) subject to paragraph (3), give the name or names of the person or persons whom the contractor wishes the Relevant Body to enter into a general dental services contract with; and

- (c) confirm that the person or persons so named meet the conditions set out in section 28M of the Act (persons eligible to enter into GDS contracts)(43) and regulations 4 and 5 (where applicable) of the GDS Contracts Regulations or, where the contractor is not able so to confirm, the reason why it is not able to do so and confirmation that the person or persons immediately prior to entering into the general dental services contract will meet those conditions.
- (3) A person's name may only be given in a notice referred to in paragraph (1) if that person is a party to the agreement.
- (4) The Relevant Body shall acknowledge receipt of the notice served under paragraph (1) within the period of seven days beginning on the day that it received the notice.
- (5) Provided that the conditions set out in section 28M of the Act and regulations 4 and 5 (where applicable) of the GDS Contracts Regulations are met, the Relevant Body shall enter into a general dental services contract with the person or persons named in the notice served under paragraph (1).
- (6) In addition to the terms required by the Act and the GDS Contracts Regulations, a general dental services contract entered into pursuant to this regulation shall provide for—
 - (a) the general dental services contract to commence immediately after the termination of the agreement;
 - (b) the same services to be provided under the general dental services contract as were provided under the agreement immediately before it was terminated unless the parties otherwise agree;
 - (c) the contractor to complete any course of treatment or orthodontic course of treatment that were not complete immediately before the agreement was terminated—
 - (i) in accordance with the terms of the general dental services contract in so far as those terms correspond with the terms of the agreement immediately before it was terminated, and
 - (ii) subject to such terms of the general dental services contract that permits the termination of a course of treatment or orthodontic course of treatment; and
 - (d) unless the parties otherwise agree—
 - (i) subject to paragraph (ii), the same number of units of dental activity or units of orthodontic activity (as the case may be) specified in the agreement in a term giving effect to regulation 13 or 14 to be provided under the general dental services contract;
 - (ii) where the general dental services contract is to begin on a day other than 1st April, the contractor to provide under that contract during the remainder of that financial year any units of dental activity or units of orthodontic activity that the contractor would have been obliged to provide in that financial year under the agreement but had not yet provided immediately before the general dental services contract begins;
 - (e) unless the parties otherwise agree—
 - (i) subject to paragraph (ii), the same number of courses of treatment involving the provision of sedation services or domiciliary services specified in the agreement in a term giving effect to regulation 16 to be provided under the general dental services contract;
 - (ii) where the general dental services contract is to begin on a day other than 1st April, the contractor under that contract to provide or contribute to during the remainder of that financial year any courses of treatment involving the provision of sedation services or domiciliary services that the contractor would have been obliged to provide or

(43) Section 28M was inserted into the Act by section 172(1) of the 2003 Act.

contribute to in that financial year under the agreement but had not yet provided or contributed to immediately before the general dental services contract begins;

- (f) in respect of a course of treatment or orthodontic course of treatment falling within subparagraph (c), the contractor to ensure that a patient who is not an exempt person only pays one NHS Charge in respect of that course of treatment or orthodontic course of treatment; and
- (g) the contractor to comply with the term of the general dental services contract giving effect to paragraph 12 of Schedule 3 to the GDS Contracts Regulations (repair or replacement of restorations) in respect of any patients to whom it provided treatment under its agreement, in addition to patients to whom it provides treatment under the general dental services contract.

(7) An agreement shall terminate on the date stated in the notice given by the contractor under paragraph (1) unless a different date is agreed by the contractor and the Relevant Body or no general dental services contract is entered into by the Relevant Body pursuant to this regulation.

(8) Where there is a dispute as to whether or not a person satisfies the conditions set out in section 28M of the Act or regulation 4 or 5 of the GDS Contracts Regulations, the contractor may appeal to the FHSAA and the Relevant Body shall be the respondent.

(9) Any other dispute relating to this regulation shall be determined by the Secretary of State in accordance with regulation 8(3) and (4) of the GDS Contracts Regulations (pre-contract disputes).

(10) The parties to a dispute referred to the Secretary of State in accordance with paragraph (9) shall be the contractor and the Relevant Body.

PART 7

TRANSITIONAL PROVISION

Commencement of agreement

22. The agreement shall provide for services to be provided under it from any date after 31st March 2006.

Signed by authority of the Secretary of State for Health

7th December 2005

Rosie Winterton
Minister of State,
Department of Health

SCHEDULE 1

Regulation 11

ADDITIONAL SERVICES

PART 1

ADVANCED MANDATORY SERVICES, DOMICILIARY SERVICES AND SEDATION SERVICES

Provision of advanced mandatory services, domiciliary services and sedation services by the contractor

1.—(1) A contractor which provides domiciliary services or sedation services under the agreement may only provide those services—

- (a) to a person to whom it is providing an entire course of treatment, during that course of treatment; or
- (b) as a referral service.

(2) A contractor may only provide advanced mandatory services under the agreement as a referral service.

(3) In this paragraph, “entire course of treatment” means a course of treatment provided by only the contractor.

Referral services

2.—(1) A contractor which provides one or more of the additional services specified in paragraph 1 as a referral service shall, at the time of the first examination of the patient, ensure that the patient is provided with a referral 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) the particulars of the places where the patient will receive the referral service to be provided to him by the contractor;
- (d) the telephone number at which the contractor may be contacted during its normal surgery hours;
- (e) details of the services which are at the date of that examination considered to be necessary for the contractor to provide having regard to the reason for the referral; and
- (f) 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) Where the services included in the referral treatment plan need to be varied for clinical reasons, the contractor shall provide the patient with a revised referral treatment plan in accordance with sub-paragraph (1).

(3) The contractor shall, subject to the termination of, or being unable to complete a course of treatment in accordance with paragraph 7(5) or (6) of Schedule 3 (course of treatment), provide the services which are detailed in the referral treatment plan, or where a revised treatment plan is provided pursuant to sub-paragraph (2), pursuant to that revised treatment plan.

(4) This paragraph shall not apply where a patient has been referred to the contractor for advanced mandatory services limited only to examination and advice, and the contractor only provides examination and advice in respect of that patient.

Sedation services

3. The contractor shall only provide sedation services to a patient in accordance with the recommendations contained in the report of the Standing Dental Advisory Committee entitled “Conscious Sedation in the Provision of Dental Care”(44), in so far as those recommendations and guidelines are relevant to—

- (a) the type of sedation being administered; and
- (b) the patient to whom the sedation is being administered.

PART 2

ORTHODONTIC SERVICES

Patients to whom orthodontic services may be provided

4.—(1) An agreement that includes the provision of orthodontic services shall specify that orthodontic services may be provided to—

- (a) only persons who are under the age of 18 years at the time of the case assessment;
- (b) only persons who have attained the age of 18 years at the time of the case assessment; or
- (c) persons falling within paragraph (a) or (b).

(2) Where an agreement specifies the matters referred to in sub-paragraph (1)(b) or (1)(c), it shall in addition specify the circumstances in which orthodontic services may be provided to a person over the age of 18 years at the time of a case assessment.

(3) The contractor shall only provide orthodontic treatment to a person who is assessed by the contractor following a case assessment as having a treatment need in—

- (a) grade 4 or 5 of the Dental Health Component of the Index of Orthodontic Treatment Need(45), or
- (b) grade 3 of the Dental Health Component of that Index with an Aesthetic Component of 6 or above,

unless the contractor is of the opinion, and has reasonable grounds for its opinion, that orthodontic treatment should be provided to a person who does not have such a treatment need by virtue of the exceptional circumstances of the dental and oral condition of the person concerned.

(4) In a case where a person does not have a treatment need but the contractor has reasonable grounds for its opinion that orthodontic treatment should be provided to that person because of the exceptional circumstances of the dental and oral condition of that person, such treatment as is referred to in sub-paragraph (3) may be provided.

(44) The Standing Dental Advisory Committee is a statutory body established under section 6 of the Act. A copy of the Report can be obtained at www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle.

(45) The Development of an Index for Orthodontic Treatment Priority: European Journal of Orthodontics 11, p.309-332, 1989 Brooke PH and Shaw WC. The article is available at www.dh.gov.uk.

Orthodontic course of treatment

5.—(1) Subject to sub-paragraph (2), the contractor shall provide orthodontic services to a patient by providing to that patient an orthodontic course of treatment.

(2) The contractor may provide orthodontic services that are not provided by virtue of an orthodontic course of treatment where—

- (a) it provides a repair to an orthodontic appliance of a person; and
- (b) the orthodontic course of treatment in which that orthodontic appliance was provided is being provided by another contractor, hospital or relevant service provider under Part 1 of the Act.

(3) The contractor shall use its best endeavours to ensure that an orthodontic course of treatment is completed within a reasonable time from the date on which the orthodontic treatment plan was written in accordance with paragraph 6(1).

(4) If an orthodontic course of treatment is—

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

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

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

- (a) the contractor—
 - (i) when the circumstances referred to in paragraph 3(1) of Schedule 3 (violent patients) 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 Schedule 3 (refusal to pay NHS Charges prior to the commencement of, or during, treatment); or
 - (iii) where, in the reasonable opinion of the contractor, there has been an irrevocable breakdown in the relationship between the patient and that 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) of Schedule 3 acting on the patient's behalf.

Orthodontic treatment plans

6.—(1) Where the contractor has, following a case assessment, determined that orthodontic treatment should be provided to a patient, it shall, at the time of that case assessment, ensure that the patient is provided with an orthodontic 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 orthodontic treatment;
- (d) the telephone number at which the contractor may be contacted during normal surgery hours;
- (e) details of the orthodontic treatment which is, 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) subject to paragraph 11 of Schedule 3 (mixing of services provided under the contract with private services), 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 orthodontic 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 private services.

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

(4) Subject to paragraphs 5(4) and (5), the contractor shall provide the orthodontic services which are detailed in the orthodontic treatment plan provided pursuant to sub-paragraph (1) or, where the orthodontic treatment plan is revised, pursuant to the revised orthodontic treatment plan.

Monitoring outcomes

7.—(1) The agreement shall require the contractor to monitor, in accordance with this paragraph, the outcome of the orthodontic treatment it provides.

(2) The contractor shall, in respect of orthodontic courses of treatment it provides in which orthodontic treatment is provided following the case assessment, monitor the outcome of that orthodontic treatment in accordance with sub-paragraph (3).

(3) The contractor shall monitor the outcome of orthodontic treatment in accordance with “Methods to determine outcome of orthodontic treatment in terms of improvement and standards”(46) in respect of—

- (a) where the total number of cases is 20 or fewer, all the cases of orthodontic courses of treatment it provides; or
- (b) where the total number of orthodontic courses of treatment provided is greater than 20—
 - (i) 20 of the cases; and
 - (ii) in addition, 10 per cent of the number of cases over 20,
 of orthodontic courses of treatment it provides.

(4) The agreement shall specify the period of time which is relevant for calculating the number of orthodontic courses of treatment that need to be monitored in accordance with this paragraph.

(5) As part of its monitoring of the outcome of orthodontic treatment under paragraph (2), the contractor shall, in respect of the patients whose courses of treatment are monitored calculate a peer assessment rating of the patient’s study casts—

- (a) taken at or after the case assessment but prior to the commencement of orthodontic treatment; and
- (b) taken at the completion of the orthodontic course of treatment,

(46) European Journal of Orthodontics 14, p125-139, 1992 Richmond S, Shaw W.C, Anderson M and Roberts C.T. The article is available at www.dh.gov.uk.

using either Clinical Outcome Monitoring Program software⁽⁴⁷⁾ or by applying the methodology set out in “An introduction to Occlusal Indices”⁽⁴⁸⁾.

(6) In sub-paragraph (5), “peer assessment rating” means an index of treatment standards in which individual scores for the components of alignment and occlusion are summed to calculate an overall score comparing pre- and post- treatment⁽⁴⁹⁾.

Completion of orthodontic courses of treatment

8.—(1) The contractor shall indicate on the form supplied to the Relevant Body pursuant to paragraph 39 of Schedule 3 (notification of a course of treatment) whether or not the orthodontic course of treatment was completed.

(2) If the Relevant Body requests in writing that the contractor provides reasons for the failure to complete one or more orthodontic courses of treatment, the contractor shall, within such period as the Relevant Body may specify, provide the reasons for that failure.

(3) If the Relevant Body—

- (a) determines that the number of orthodontic 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 orthodontic courses of treatment are satisfactory,

it shall be entitled to exercise its powers under paragraph 71 of Schedule 3 on the grounds that the contractor is not, pursuant to paragraph 5(3), using its best endeavours to ensure orthodontic courses of treatment are completed.

SCHEDULE 2

Regulations 13 and 14

PROVISION OF SERVICES: UNITS OF DENTAL ACTIVITY AND UNITS OF ORTHODONTIC ACTIVITY

PART 1

UNITS OF DENTAL ACTIVITY

1.—(1) Where the contractor provides a banded course of treatment, the contractor provides the number of units of dental activity specified in the appropriate row of Table A.

(2) Where a banded course of treatment is commenced but not completed for whatever reason, the appropriate number of units of dental activity provided shall be calculated on the basis of the components of the course of the treatment which has been—

- (a) completed;
- (b) commenced but not completed.

⁽⁴⁷⁾ Clinical Outcome Monitoring Program – Version 3.1 for Windows 98, XP and 2000. See also Weerakone S and Dhopatkar “A: Clinical Outcome Monitoring Program (COMP): a new application for use in orthodontic audits and research”, American Journal of Orthodontics and Dentofacial Orthopaedics 2003;123: 503-511.

⁽⁴⁸⁾ Richmond, O'Brien, Buchanan and Burden, 1992, Victoria, University of Manchester, ISBN 1-898922-00-4.

⁽⁴⁹⁾ A description of this methodology can be found in the European Journal of Orthodontics 14, p180-187, 1992, Richmond S, Shaw WC, Roberts CT and Andrews M: “Methods to determine the outcome of orthodontic treatment in terms of improvement and standards”.

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

2. Where the contractor provides a charge exempt course of treatment, the contractor provides the number of units of dental activity specified in the appropriate row of Table B.

Table A

Units of dental activity provided under the agreement in respect of banded courses of treatment.

<i>Type of course of treatment</i>	<i>Units of dental activity provided</i>
Band 1 course of treatment (excluding urgent treatment)	1.0
Band 1 course of treatment (urgent treatment only)	1.2
Band 2 course of treatment	3.0
Band 3 course of treatment	12.0

Table B

Units of dental activity provided under the agreement in respect of charge exempt courses of treatment

<i>Type of charge exempt course of treatment</i>	<i>Units of dental activity provided</i>
Issue of a prescription	0.75
Repair of a dental appliance (denture)	1.0
Repair of a dental appliance (bridge)	1.2
Removal of sutures	1.0
Arrest of bleeding	1.2

PART 2

UNITS OF ORTHODONTIC ACTIVITY

3.—(1) Where the contractor provides an orthodontic course of treatment to a patient that solely consists of a case assessment, the contractor provides 1.0 unit of orthodontic activity.

(2) Where the contractor provides an orthodontic course of treatment to a patient aged under 10 years that consists of—

- (a) a case assessment; and
- (b) the provision of orthodontic treatment following the case assessment,

the contractor provides 4.0 units of orthodontic activity.

(3) Where the contractor provides an orthodontic course of treatment to a patient aged between 10 and 17 years of age that consists of—

- (a) a case assessment; and
- (b) the provision of orthodontic treatment to the patient following the case assessment,

the contractor provides 21.0 units of orthodontic activity.

(4) Where the contractor provides an orthodontic course of treatment to a patient who is aged 18 years or over that consists of—

- (a) a case assessment; and

(b) the provision of orthodontic treatment to the patient,
the contractor provides 23.0 units of orthodontic activity.

(5) Where the contractor—

- (a) provides a repair to an orthodontic appliance of a patient; and
- (b) the orthodontic course of treatment in which that orthodontic appliance was provided is being provided by another contractor, hospital or relevant service provider under Part 1 of the Act,

the contractor provides 0.8 units of orthodontic activity.

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⁽⁵⁰⁾; 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.

(50) 1989 c. 41.

(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.

(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—

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

(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
- (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⁽⁵¹⁾, in particular the guidance entitled “Dental recall - Recall interval between routine dental examinations”⁽⁵²⁾.

Infection control

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

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”⁽⁵³⁾.

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—

⁽⁵¹⁾ The National Institute for Clinical Excellence is established as a Special Health Authority under section 11 of the Act.

⁽⁵²⁾ This guidance is available from NICE’s website, www.nice.org.uk.

⁽⁵³⁾ <http://www.gdc-uk.org/News+publications+and+events/Publications/Guidance+documents?Standards+for+dental+professionals.htm>.

- (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.

PART 4

PERSONS WHO PERFORM SERVICES

Dental practitioners

- 22.** A dental practitioner⁽⁵⁴⁾ 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⁽⁵⁵⁾ (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⁽⁵⁶⁾.

- (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⁽⁵⁷⁾ 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.

⁽⁵⁴⁾ The term dental practitioner is defined in section 128 of the Act as a person registered in the dentists register under the Dentists Act.

⁽⁵⁵⁾ Section 36A is prospectively inserted into the Dentists Act by article 29 of the Dentists Act Order.

⁽⁵⁶⁾ *S.I. 1986/887*; relevant amending instruments are *S.I. 1999/3460* and *2002/1671*.

⁽⁵⁷⁾ Section 36B is prospectively inserted into the Dentists Act by article 29 of the Dentists Act Order.

(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.

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—

- (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⁽⁵⁸⁾ (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;

⁽⁵⁸⁾ S.I. 2002/618.

- (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.

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⁽⁵⁹⁾ (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;

⁽⁵⁹⁾ Section 16CA was inserted into the Act by section 170 of the 2003 Act.

- (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⁽⁶⁰⁾ (definition of inability to pay debts).

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⁽⁶¹⁾ 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⁽⁶²⁾ (right of entry).

⁽⁶⁰⁾ 1986 c. 45.

⁽⁶¹⁾ S.I. 2003/2124.

⁽⁶²⁾ 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⁽⁶³⁾ (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⁽⁶⁴⁾; 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.

⁽⁶³⁾ Section 19A was inserted by the Health and Social Care Act 2001 (c. 15), section 12.

⁽⁶⁴⁾ 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⁽⁶⁵⁾;
 - “local authority” means—
 - (a) any of the bodies listed in section 1 of the Local Authority Social Services Act 1970⁽⁶⁶⁾ (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⁽⁶⁷⁾ (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—

⁽⁶⁵⁾ 1978 c. 29.

⁽⁶⁶⁾ 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.

⁽⁶⁷⁾ 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⁽⁶⁸⁾.
- (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

⁽⁶⁸⁾ 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

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⁽⁶⁹⁾ 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⁽⁷⁰⁾ (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⁽⁷¹⁾ (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;

⁽⁶⁹⁾ 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.

⁽⁷⁰⁾ 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.

⁽⁷¹⁾ 1995 c. 46.

- (ii) been made the subject of a bankruptcy restrictions order or an interim bankruptcy restrictions order under Schedule 4A to the Insolvency Act 1986⁽⁷²⁾, 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⁽⁷³⁾;
 - (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⁽⁷⁴⁾ (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⁽⁷⁵⁾, the Companies (Northern Ireland) Order 1986⁽⁷⁶⁾ 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—

⁽⁷²⁾ 1986 c. 45. Schedule 4A was inserted by section 257 of, and Schedule 3 to, the Enterprise Act 2002 (c. 40).

⁽⁷³⁾ Schedule B1 was inserted by section 248 of, and Schedule 16 to, the Enterprise Act 2002.

⁽⁷⁴⁾ 1990 c. 40.

⁽⁷⁵⁾ 1986 c. 46; as amended by the Insolvency Act 2000 (c. 39).

⁽⁷⁶⁾ 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(77) (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(78) (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—

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

(78) 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.

SCHEDULE 4

Regulation 20 and paragraph 35 of
Schedule 3

PATIENT INFORMATION LEAFLET

A patient leaflet shall include—

1. The name of the party or parties comprising the contractor.
2. In the case of an agreement with a qualifying body—
 - (a) the names of the directors, chief executive and secretary of that body, in so far as those positions exist in relation to the qualifying body; and
 - (b) the address of that body's registered office.
3. The full name of each person performing services under the agreement.
4. In the case of each person performing dental services under the agreement, his professional qualifications.
5. Whether the contractor undertakes the teaching or training of persons who provide dental services or who intend to do so.
6. The address of each of the practice premises.
7. The contractor's telephone and fax numbers and the address of its website (if any).
8. Whether the practice premises have suitable access for disabled patients and, if not, the alternative arrangements for providing services to such patients.
9. How to request services as a patient.
10. The rights of a patient to express a preference of practitioner in accordance with paragraph 2 of Schedule 3 and the means of expressing such a preference.
11. The services available under the agreement.
12. The normal surgery days and hours of the practice.
13. The arrangements for the dental hours and days that fall outside normal surgery hours (whether or not provided by the contractor) and how the patient may contact such services.
14. If the services in paragraph 13 are not provided by the contractor, the fact that the Relevant Body referred to in paragraph 20 is responsible for commissioning the services.
15. The telephone number of NHS Direct and details of NHS Direct online.
16. How patients may make a complaint or comment on the provision of services.
17. The rights and responsibilities of the patient, including keeping appointments.

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18. The action that may be taken where a patient is violent or abusive to the contractor, its staff, persons present on the practice premises or in the place where treatment is provided under the agreement or other persons specified in paragraph 3(2) of Schedule 3.

19. Details of who has access to patient information (including information from which the identity of the individual can be ascertained) and the patient's rights in relation to disclosure of such information.

20. The name, postal and website address and telephone number of the Relevant Body with which the contractor is a party to the agreement.

21. The fact that details of primary dental services in the area may be obtained from the Relevant Body or, where the contractor is a Primary Care Trust, that Primary Care Trust.

SCHEDULE 5

Regulation 20

MODIFICATION OF PATIENT PROVISIONS WHERE THE CONTRACTOR IS A PRIMARY CARE TRUST

1. Paragraphs 3 and 5 of Schedule 3 shall apply as modified by paragraphs 2 and 3 respectively where the contractor is a Primary Care Trust.

2. As if for paragraph 3, there were substituted the following—

“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 Primary Care Trust may notify that patient that it will no longer provide services to him under the agreement.

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

- (a) any member of the Primary Care Trust's staff;
- (b) a person engaged by the Primary Care Trust to perform or assist in the performance of services under the agreement; or
- (c) 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. As if for paragraph 5, there were substituted the following—

“Irrevocable breakdown in relationship between contractor and patient

5.—(1) 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 no longer provide services to that patient under the agreement.”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set out, for England, the framework for personal dental services agreements under section 28C of the National Health Service Act 1977 (“the Act”).

Part 2 of the Regulations prescribes the conditions which, in accordance with section 28D of the Act, must be met by a contractor before the Relevant Body may enter into a personal dental services agreement with it.

Part 3 of the Regulations prescribes the procedure for pre-agreement dispute resolution, in accordance with section 28E(3D) of the Act. Part 3 applies to cases where the contractor is not a health service body. In cases where the contractor is such a body, the procedure for dealing with pre-contract disputes is set out in section 4 of the National Health Service and Community Care Act 1990 (“the 1990 Act”).

Part 4 of the Regulations provides for a contractor to be a health service body for the purposes of section 4 of the 1990 Act unless it objects by serving a notice on the Relevant Body before the agreement is made.

Part 5 of (and Schedules 1 to 3 to) the Regulations prescribe the terms which, in accordance with section 28E of the Act, must be included in a personal dental services agreement.

The prescribed terms include terms relating to—

- (a) whether the agreement is an NHS contract (regulation 10);
- (b) the services to be provided and the manner in which they are to be provided (regulations 11 to 14 and 16 and Schedules 1 and 2 and Parts 1 and 2 of Schedule 3);
- (c) finance, fees and charges (regulations 17 and 18);
- (d) prescribing of drugs and appliances (Schedule 3, Part 3);
- (e) the conditions to be met by those who perform services or are employed or engaged by the agreement (Schedule 3, Part 4);
- (f) patient records, the provision of information and rights of entry and inspection (Schedule 3, Part 5);
- (g) complaints (Schedule 3, Part 6);
- (h) procedures for dispute resolution (Schedule 3, Part 7);
- (i) procedure for a mid-year review of activity under the agreement (Schedule 3, Part 8); and
- (j) procedures for variation and termination of agreements (Schedule 3, Part 9).

Part 6 of the Regulations provides for the contractor to terminate its agreement and enter into a general dental services contract.

Part 7 of the Regulations makes transitional provision.

A Regulatory Impact Assessment has been prepared for these Regulations and a copy has been placed in the library of each House of Parliament. A copy of the Regulatory Impact Assessment can be obtained from www.dh.gov.uk/ria.

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