
WELSH STATUTORY INSTRUMENTS

2006 No. 489

The National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006

PART 1

GENERAL

Title, commencement and application

1.—(1) The title of these Regulations is the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006 which come into force on 1 March 2006.

(2) These Regulations apply in relation to Wales.

Interpretation

2.—(1) In these Regulations—

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

“the Assembly” means the National Assembly for Wales;

“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 Assembly or a person or persons appointed by the Assembly 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 Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(1);

“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,

which, by virtue of regulation 3(2)(d) or (f) 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 Schedule 1) has been provided to the patient,

and “completed” will be construed accordingly;

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

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

“course of treatment” means—

- (a) an examination of a patient, an assessment of his or her 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⁽²⁾;

“dental performers list” means a list of dental practitioners prepared in accordance with regulations made under section 28X of the Act⁽³⁾ (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⁽⁴⁾ (dental public health);

“Dentists Act” means the Dentists Act 1984⁽⁵⁾;

“Dentists Act Order” means the Dentists Act 1984 (Amendment) Order 2005⁽⁶⁾;

“Dentists Register” means the register maintained by the General Dental Council pursuant to section 14 of the Dentists Act⁽⁷⁾ (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⁽⁸⁾ (dental charging: exemptions) or the NHS Charges Regulations, exempt from the need to pay an NHS Charge in respect of the services he or she has received under the agreement;

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

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

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

(5) [1984 c. 24](#).

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

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

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

“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⁽⁹⁾; or
- (h) a grandparent;

“FHSAA” means the Family Health Services Appeal Authority constituted under section 49S of the Act⁽¹⁰⁾ (the Family Health Services Appeal Authority);

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

“GDS Contracts Regulations” means the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006⁽¹¹⁾;

“health care professional” has the same meaning as in section 28M of the Act⁽¹²⁾ (persons eligible to enter into GDS contracts) and “health care profession” will 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 (NHS contracts)⁽¹³⁾;

“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 Assembly for the purposes of section 41(1)(c) of the Act⁽¹⁴⁾ (arrangements for pharmaceutical services);

“Local Health Board” means, except where the context otherwise requires, the Local Health Board which is a party, or prospective party, to an agreement;

“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⁽¹⁵⁾ (national disqualifications);

⁽⁹⁾ 1989 c. 41.

⁽¹⁰⁾ Section 49S was inserted into the Act by section 27(1) of the 2001 Act.

⁽¹¹⁾ S.I. 2006/490 (W.59).

⁽¹²⁾ Section 28M was inserted into the Act by section 172(1) of the 2003 Act.

⁽¹³⁾ Section 4(2) was amended by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 68, the 1999 Act, Schedule 4, paragraph 76(a) and Schedule 5, the 2002 Act, Schedule 1, paragraph 40 and Schedule 5, paragraph 31.

⁽¹⁴⁾ 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 2, 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.

⁽¹⁵⁾ 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.

- (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⁽¹⁶⁾ or regulation 6(4)(b) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002⁽¹⁷⁾;

“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) (Wales) Regulations 2006⁽¹⁸⁾;

“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⁽¹⁹⁾ for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14 December 2001 and in relation to Wales only until 26 August 2002⁽²⁰⁾;

“normal surgery hours” means the times at which the contractor has agreed with the Relevant Body (and specified in the agreement) that that 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⁽²¹⁾;

“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;

⁽¹⁶⁾ S.I. 2001/3744 amended by S.I. 2002/2469.

⁽¹⁷⁾ S.I. 2002/1920.

⁽¹⁸⁾ S.I. 2006/491 (W.60).

⁽¹⁹⁾ Section 46 was revoked by the 2001 Act, section 67, Schedule 5, paragraph 5 and Schedule 6, Part 1.

⁽²⁰⁾ 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.

⁽²¹⁾ S.I. 2001/1743.

“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⁽²²⁾;
- (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 sections 39, 42 or 43 of the Act;
- (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⁽²³⁾;
- (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 and 36 of the Act⁽²⁴⁾;
- (e) a services list which fell within the meaning of section 8ZA of the National Health Service (Primary Care) Act 1997⁽²⁵⁾;
- (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⁽²⁶⁾; or
- (g) a list corresponding to any of the above lists in Scotland or Northern Ireland;

“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⁽²⁷⁾ (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” will 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—

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

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

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

(25) 1997 c. 46. Section 8ZA was inserted into the Act by section 26(2) of the 2001 Act and repealed by section 196 and Schedule 14 Part 4 to the 2003 Act.

(26) 2001 c. 15.

(27) 2000 c. 6.

- (a) an alternative 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(28) (the dental care professionals register);

“Relevant Body” means in a case where a contractor is a party to an agreement with a Local Health Board, that Local Health Board;

“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 or her 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 will 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 will be construed accordingly; and

(28) Section 36B is prospectively inserted into the Dentists Act by the Dentists Act Order.

- (b) references to forms supplied by the Local Health Board 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⁽²⁹⁾, 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) of the Act 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, she or it (in the case of a qualifying body) is the subject of a national disqualification;
- (b) subject to paragraph (4), he, she 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 or she has been dismissed (otherwise than by reason of redundancy) from any employment by a health service body, unless he or she has subsequently been employed by that health service body or another health service body and paragraph (5) applies to him or her or that dismissal was the subject of a finding of unfair dismissal by any competent tribunal or court; or
 - (ii) he, she 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⁽³⁰⁾ respectively) unless his, her or its name has subsequently been included in such a list;

- (d) he or she has been convicted in the United Kingdom of—

- (i) murder; or

⁽²⁹⁾ A “qualifying body” is defined in section 28D(2) of the Act.

⁽³⁰⁾ Section 49F was inserted into the Act by section 25 of the 2001 Act.

- (ii) a criminal offence other than murder, committed on or after 26 August 2002, and has been sentenced to a term of imprisonment of over six months;
- (e) subject to paragraph (6), he or she 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 26 August 2002, 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 or she has been convicted of an offence referred to in Schedule 1 to the Children and Young Persons Act 1933⁽³¹⁾ (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⁽³²⁾ (offences against children under the age of 17 years to which special provisions apply) committed on or after 1 April 2006;
- (g) he, she or it has—
 - (i) been adjudged bankrupt or had sequestration of his or her estate awarded unless (in either case) he or she 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⁽³³⁾ 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, her or its creditors unless he, she or it has been discharged in respect of it;
- (h) an administrator, administrative receiver or receiver is appointed in respect of it;
- (i) he or she has within the period of five years prior to the date the contract is to be commenced or, if earlier, the date on which the contract 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 or she was responsible or to which he or she was privy, or which he or she by his or her conduct contributed to or facilitated;
 - (ii) been removed under section 7 of the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990⁽³⁴⁾ (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⁽³⁵⁾, the Companies (Northern Ireland) Order 1986⁽³⁶⁾ or to an order made under section 429(2)(b) of the Insolvency Act 1986⁽³⁷⁾ (failure to pay under county court administration order).

⁽³¹⁾ 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.

⁽³²⁾ 1995 c. 46.

⁽³³⁾ 1986 c. 45. Schedule 4A was inserted by section 257 of, and Schedule 20 to, the Enterprise Act 2002 (c. 40).

⁽³⁴⁾ 1990 c. 40.

⁽³⁵⁾ 1986 c. 46 as amended by the Insolvency Act 2000 (c. 39).

⁽³⁶⁾ S.I. 1986/103N (N.I. 6).

⁽³⁷⁾ 1986 c. 45.

(4) A person will 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;
- (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.

(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 will 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 43 of the Dentists Act.

(2) Paragraph (1) will 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 will 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, her, its, or their right of appeal under regulation 7.

(2) The Relevant Body will 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 relates 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 twenty eight 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 Assembly 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 Assembly in accordance with paragraph (1), or section 4(4) of the 1990 Act, will 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 Assembly 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) will be binding upon the prospective parties to the agreement.

PART 4

HEALTH SERVICE BODY STATUS

Health service body status

9.—(1) A contractor will 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 will 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 will 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 will agree to the variation; and
- (b) the procedure in paragraph 60(1) of Schedule 3 (variation of a contract: general) will apply.

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

- (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, will 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 will 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 will, 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 1 (dispute resolution: non-NHS contracts);
- (c) paragraph (6), it will 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 1 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 1 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 1 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 1 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 will provide that the Relevant Body will 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 5 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 time period as the Relevant Body specifies in writing, such period to consist of not less than sixty days.

(3) Paragraphs (1) and (2) will 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 twelve months, the period of sixty days in paragraph 2 (ii) may not apply if the Relevant Body considers it not appropriate or considers that another period of less than sixty 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 1 April, in each financial year; or
- (ii) where the contract begins on a date other than 1 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 Assembly under section 28E(3A) of the Act⁽³⁸⁾ (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 Assembly under section 16BB(4) (Local Health Board's functions)⁽³⁹⁾ 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 Assembly under section 28E(3A).

(3) The agreement must contain a term to the effect that where, pursuant to directions under section 16BB(4) 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).

⁽³⁸⁾ Section 28E(3A) was inserted by section 177(8) of the 2003 Act.

⁽³⁹⁾ Section 16BB of the Act was inserted by section 6(1) of the 2002 Act

(2) The contractor will 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 herself or a family member, as a prerequisite to providing services under the agreement to that person or his or her 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.

(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) will have the same meaning as in regulation 2(1) of the NHS Charges Regulations.

Arrangements on termination

19. An agreement will 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) will have effect in relation to the matters set out in those paragraphs.

(3) Where an agreement does not commence on 1 April in any financial year or the duration of an agreement is less than twelve 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 will 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) will—

- (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)(**40**) 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 will 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 will 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 will 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 courses of treatment or orthodontic courses of treatment that were not complete immediately before the agreement was terminated—
 - (i) in accordance with the terms of the general dental services contract insofar 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 courses of treatment; and
- (d) unless the parties otherwise agree—

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

- (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 1 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 1 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 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 courses 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 11 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 will 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 of the GDS Contracts Regulations, the contractor may appeal to the FHSAA and the Relevant Body will be the respondent.

(9) Any other dispute relating to this regulation will be determined by the Assembly 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 Assembly in accordance with paragraph (9) will be the contractor and the Relevant Body.

PART 7

TRANSITIONAL PROVISION

Commencement of agreement

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

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(41)

28 February 2006

D. Elis-Thomas
The Presiding Officer of the National Assembly