DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The National Health Service (Dental Services) (Prototype Agreements) Directions 2015

The Secretary of State for Health makes the following Directions in exercise of the powers conferred by sections 114A(3), 272(7) and (8) and 273(1) of the National Health Service Act 2006(a).

PART 1

General

Citation, commencement and duration

- 1.—(1) These Directions may be cited as the National Health Service (Dental Services) (Prototype Agreements) Directions 2015 and come into force on 1st November 2015.
 - (2) These Directions will cease to have effect at the end of 31st March 2018.
 - (3) These Directions are given to the Board.

Interpretation

2.—(1) In these Directions—

"the Act" means the National Health Service Act 2006;

"the Board" means the National Health Service Commissioning Board(b);

"Blend A prototype agreement" means a prototype agreement of that name with the Blend A remuneration model that is assigned to a group of prototype agreements to enable the evaluation of different methods of payment for services provided under prototype agreements for the purposes of the objectives of the Prototype Agreements Scheme;

"Blend B prototype agreement" means a prototype agreement of that name with the Blend B remuneration model that is assigned to a group of prototype agreements to enable the evaluation of different methods of payment for services provided under prototype agreements for the purposes of the objectives of the Prototype Agreements Scheme;

"Capitation and Quality Scheme" means the scheme of that name that the Secretary of State developed to assist in continuing to promote and secure improvement in the provision of dental services in accordance with the Act which ended on 31st March 2013;

"Capitation and Quality Scheme 2 Agreement" means an Agreement which formed a temporary part of a GDS Contract or PDS Agreement and which was entered into as part of the Capitation and Quality Scheme 2 introduced by the Secretary of State on 1st April 2013,

⁽a) 2006 c.41. Section 114A was inserted into the National Health Service Act 2006 by section 49(2) of the Health and Social Care Act 2012 (c.7). By virtue of section 271(1) of the National Health Service Act 2006, the functions of the Secretary of State being exercised in the making of these Directions are exercisable only in relation to England.

⁽b) The National Health Service Commissioning Board was established by section 1H of the National Health Service Act 2006. Section 1H was inserted by section 9 of the Health and Social Care Act 2012 (c.7).

and in accordance with the National Health Service (Dental Services) (Capitation and Quality Scheme 2 Agreements) Directions 2013(a);

"Capitation and Quality Scheme 2" means the scheme of that name, introduced by the Secretary of State on 1st April 2013, following the termination of the Capitation and Quality Scheme on 31st March 2011, that the Secretary of State has developed to assist in continuing to promote and secure improvement in the provision of dental services in accordance with the Act:

"Capitation and Quality Scheme 2 Statement of Financial Entitlements" means the directions made by the Secretary of State under sections 103(1) and 109(4) of the Act, which applied where a contractor and the Board elected to enter into a Capitation and Quality Scheme 2 Agreement;

"contractor" means a person other than the Board who is a party to a GDS agreement or a PDS agreement;

"GDS contract" means a general dental services contract within the meaning of section 100 of the 2006 Act (general dental services: introductory);

"GDS Contracts Regulations" means the National Health Service (General Dental Services Contracts) Regulations 2005(**b**);

"GDS SFE" means the General Dental Services Statement of Financial Entitlements 2013(c);

"interim care plan" means the plan of the additional advice and preventative treatment proposed at a patient's oral health assessment or oral health review which is recorded on a patients treatment plan, which includes—

- (a) proposals of any preventative treatment to be provided;
- (b) proposals for instruction on techniques and practices required in relation to the promotion of oral health; and
- (c) proposals in respect of advice in relation to diet, hygiene, personal habits and oral health in order to prevent dental and oral disease;

"the NAAV" means the negotiated annual agreement value of a PDS Agreement determined by section 2 of the PDS SFE;

"the NACV" means the negotiated annual contract value of a GDS contract determined by section 2 of the GDS SFE;

"NHS Charges Regulations" has the meaning given in regulation 2 of the GDS Contracts Regulations (interpretation);

"oral health assessment" means the initial examination at which a comprehensive and standardised assessment of a patient's oral health and individual risk factors relating to oral health is carried out when that patient first visits a practice holding a prototype agreement which includes—

- (a) clinical assessment of that patient; and
- (b) a review of that patient's medical history and clinically relevant social history, where relevant to a patient's oral health,

⁽a) The National Health Service (Dental Services) (Capitation and Quality Scheme Agreements) Directions 2013 signed on 13th March 2013 is available on www.gov.uk. A hard copy of these Directions can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS

⁽b) S.I. 2005/3361; as amended by S.I. 2006/563, 2007/544, 2008/528, 1514, and 1700, 2009/309 and 462, 2010/22 and 1181, 2011/1182, 2012/502, 2273 and 2404, 2013/364, 2014/443 and 1887 and 2015/137 and 416.

⁽c) General Dental Services Statement of Financial Entitlements 2013 signed on 28th March 2013 as amended by: The Primary Dental Services Statements of Financial Entitlements (Amendment) Directions 2014 signed on 16th April 2014; and the Primary Dental Services Statement of Financial Entitlements (Amendment) Directions 2015 signed on 30th July 2015. All of the aforementioned sets of Directions are available on www.gov.uk. A hard copy of these Directions can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS.

during which the provider of services and the patient agree a self-care plan and a care pathway incorporating advice, actions to be undertaken by the patient and treatment for that patient that is appropriate to that patient's needs;

"oral health review" means the examination undertaken for the purposes of updating the patient's current oral health assessment, which is scheduled according to the patient's needs and risks, at which the patient's care pathway is reviewed and agreed with the patient;

"overall business value" means the turnover of a practice in respect of the provision of dental services, whether provided as NHS services or otherwise in a financial year;

"participant" means a contractor who is a party to a prototype agreement;

"PDS agreement" means an agreement under which primary dental services are provided under section 107 of the Act(a) (arrangements by the Board for the provision of primary dental services);

"PDS Agreements Regulations" means the National Health Service (Personal Dental Services Agreements) Regulations 2005(**b**);

"the PDS SFE" means the Personal Dental Services Statement of Financial Entitlements 2013(c);

"prototype agreement" means a GDS contract or a PDS Agreement temporarily varied as part of the Prototype Agreements Scheme which contain—

- (a) the terms and conditions required under these Directions; and
- (b) the terms and conditions for such contractors required under the GDS Contracts Regulations or the PDS Agreements Regulations.

"Prototype Agreements Scheme" means the Scheme of that name, introduced by the Secretary of State on 1st November 2015 that the Secretary of State has developed to assist in continuing to promote and secure improvement in the provision of dental services in accordance with the Act;

"Prototype SFE" means the Prototype Agreements Scheme Statement of Financial $Entitlements(\mathbf{d})$;

"treatment plan" has the same meaning as in paragraph 7 of Schedule 3 to the GDS Agreements Regulations (other contractual terms - treatment plans).

(2) Expressions used in directions 3 to 19, and in whichever of the GDS Contracts Regulations, the PDS Agreements Regulations or the NHS Charges Regulations is relevant to the particular context, have the same meaning in both contexts.

⁽a) Section 107 of the National Health Service Act 2006 is amended by paragraph 48 of Schedule 4 to the Health and Social Care Act 2012 (c.7).

⁽b) S.I. 2005/3373; as amended by S.I. 2006/563, 2007/544, 2008/528 and 1514, 2009/309 and 462, 2010/22 and 1181, 2011/1182, 2012/502, 2273 and 2404, 2013/364, 2014/443 and 1887 and 2015/137 and 416.

⁽c) Personal Dental Services Statement of Financial Entitlements 2013 signed on 28th March 2013 as amended by: The Primary Dental Services Statements of Financial Entitlements (Amendment) Directions 2014 signed on 16th April 2014; and the Primary Dental Services Statement of Financial Entitlements (Amendment) Directions 2015 signed on 30th July 2015. All of the aforementioned sets of Directions are available on www.gov.uk. Hard copies of the aforementioned sets of Directions can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS.

⁽d) The Prototype Agreements Scheme Statement of Financial Entitlements signed on 23rd September 2015 is available on www.gov.uk. A hard copy of these Directions can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS.

PART 2

Prototype agreements

Directions to the Board

- **3.**—(1) The Board must, where requested to do so, consider entering into a prototype agreement with a contractor but may only do so where the Secretary of State has approved the proposal for the contractor and the Board to do so.
- (2) The Board may only enter into a prototype agreement where the Secretary of State's approval to enter into that prototype agreement has been obtained and the conditions in paragraph (3) apply.
 - (3) The conditions referred to in paragraph (2) are—
 - (a) the Secretary of State has approved the prototype agreement as being suitable to assist in the continuing promotion and development of primary dental services in order to secure such services:
 - (b) the contractor meets the eligibility conditions specified in directions 4 to 6; and
 - (c) the Board satisfies itself that the contractor understands the objectives of participating in the Prototype Agreements Scheme and understands the requirements being placed upon the contractor as a consequence of entering into the prototype agreement.
 - (4) The prototype agreement which the Board enters into—
 - (a) must be in writing;
 - (b) must contain terms and conditions that have the same effect as the terms and conditions specified in directions 7 to 19;
 - (c) must be of a duration that does not extend to any period after 31st March 2018; and
 - (d) must start at the beginning of a day and end at the end of a day.

Eligibility conditions relating to contractors who held a Capitation and Quality Scheme 2 Agreement prior to the end of 31st October 2015

- **4.** The Board must only enter into a prototype agreement with a contractor who held a Capitation and Quality Scheme 2 Agreement prior to the end of 31st October 2015—
 - (a) where the Secretary of State and the Board are satisfied that the contractor has participated in the Capitation and Quality Scheme 2 up to and including 31st March 2015;
 - (b) where the Board and the Secretary of State are satisfied that the contractor meets the eligibility conditions for holding a prototype agreement and can comply with other relevant directions; and
 - (c) where the Board and the Secretary of State are satisfied that the contractor is a suitable contractor to hold a prototype agreement, and that the contractor's participation in the Prototype Agreements Scheme will assist in the overall objectives of that Scheme.

Eligibility conditions relating to contractors who have not previously held a Capitation and Quality Scheme 2 Agreement

- **5.** The Board must only enter into a prototype agreement with a contractor who has not previously held a Capitation and Quality Scheme 2 Agreement where the contractor had entered into a PDS agreement or a GDS contract with the Board and that PDS agreement or GDS contract subsists on 31st of March 2015, and
 - (a) that PDS agreement or, as the case may be, that GDS contract had—
 - (i) at 31st of March 2015 subsisted for a period of at least 3 years, and

- (ii) immediately before the calendar month in which the prototype agreement is to commence a NAAV or, as the case may be, a NACV, which is at least £100,000 per year;
- (b) at least 51% of the NAAV of that PDS agreement or, as the case may be, the NACV of that GDS contract, is attributed to units of dental activity;
- (c) the remuneration in respect of the NHS services provided under that PDS agreement or, as the case may be, GDS contract, amounts to at least 60% of the overall business value of the practice;
- (d) the contractor has been commissioned to provide NHS dental services to every type of patient who is entitled to receive such services;
- (e) services provided under that PDS agreement, or that GDS contract, are provided for a minimum of five days a week; and
- (f) in the case of a contractor with a PDS agreement—
 - (i) mandatory services are provided under that PDS agreement, and
 - (ii) the PDS agreement terminates no earlier than 31st March 2017.

Eligibility conditions that apply to all contractors electing to enter a prototype agreement

- **6.** The Board must only enter into a prototype agreement—
 - (a) where the contractor agrees to be assigned to either a Blend A or a Blend B prototype agreement;
 - (b) where it satisfies itself that the contractor continues to be eligible to enter a PDS agreement or a GDS contract pursuant to the conditions referred to
 - (i) in the case of a contractor with a PDS agreement, in regulation 4(1) (general conditions relating to all agreements) and 5(1) (additional conditions relating to agreements with dental corporations) of the PDS Agreements Regulations, or
 - (ii) in the case of a contractor with a GDS contract, in regulation 4(1) (general prescribed conditions relating to all contracts) and 5(1) (additional prescribed conditions relating to contracts with dental corporations) of the GDS Agreements Regulations; and
 - (c) if it satisfies itself that the contractor has, at the date of the commencement of the prototype agreement, or is willing to provide at its own expense by that date, equipment (including chair-side IT), facilities and systems which—
 - (i) enable the electronic transmission of data—
 - (aa) for the purposes of meeting the objectives of the Prototype Agreements Scheme.
 - (bb) in relation to the provision of dental services under the PDS agreement or the GDS contract, and
 - (cc) at such intervals as may be reasonably proposed by the Board to the NHS Business Services Authority(a), and
 - (ii) enable the effective monitoring and evaluation of the Prototype Agreements Scheme and the analysis of any data provided as a consequence of the prototype agreement.

Orthodontic activity

7. Where orthodontic services have been provided under the PDS agreement or the GDS contract held by the participant immediately before the commencement of a prototype agreement, the Board must—

⁽a) Established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005 (S.I. 2005/2414; as amended by S.I. 2006/632, 2007/1201, and 2013/235).

- (a) agree a value for that part of the NAAV or the NACV that is attributed to orthodontic activity with the participant; and
- (b) record that value in writing in the prototype agreement.

Finance

- **8.**—(1) Subject to paragraph (2), the Board must make payments to a participant in accordance with the relevant directions given by the Secretary of State made under section 109(4) of the Act (regulations about section 107 arrangements) where primary dental services are provided under a PDS agreement or, as the case may be, under section 103(1) of the Act (GDS contracts: payments) where such services are provided under a GDS contract.
- (2) Paragraph (1) is subject to any right the Board has to set off against an amount payable to the participant an amount that—
 - (a) is owed by the participant to the Board under the prototype agreement;
 - (b) has been paid to the participant owing to an error or in circumstances when it was not due; or
 - (c) may be withheld in accordance with these Directions and any relevant directions given by the Secretary of State made under section 109(4) of the Act where primary dental services are provided under a PDS agreement, or, as the case may be, under section 103(1) of the Act where such services are provided under a GDS contract.

Variation of a prototype agreement

- **9.**—(1) Subject to direction 18, the Board must not vary the terms and conditions of the prototype agreement without the approval of the Secretary of State.
- (2) The Board may vary the terms and conditions of the prototype agreement without the participant's consent but only to the extent that it is necessary to vary the PDS Agreement or GDS contract so as to comply with the Act, any regulations made pursuant to the Act or any directions given by the Secretary of State pursuant to the Act.

Termination of a prototype agreement

- **10.**—(1) The Board must, before giving notice of its intention to withdraw from a prototype agreement in accordance with paragraph (2), discuss its intention to do so with the Secretary of State.
- (2) The Board must give a period of not less than 3 months notice to the Secretary of State and a participant of any intention to withdraw from a prototype agreement.
- (3) Without prejudice to direction 11, the Board must make suitable provision for arrangements on termination of the prototype agreement.
- (4) The participant may withdraw from a prototype agreement but must give a period of not less than 3 months notice to the Board and the Secretary of State of any intention to do so.
- (5) The Board may, in particular, consider withdrawal from a prototype agreement in the circumstances set out in paragraph (6).
 - (6) The circumstances referred to in paragraph (5) are—
 - (a) where, in the view of the Board, there has been a significant reduction in average weekly time given to appointments in which an element of NHS care is delivered and reported to the NHS Business Services Authority during the financial year;
 - (b) where a contractor's overall capitation and activity performance level is less than 90% at the end of the financial year, or where, during the financial year, it is forecast by the NHS Business Services Authority to be likely to be less than 90% at the end of the financial year;
 - (c) where, in the view of the Board, there has been a significant failure to return the information required under direction 13, or any other information required by the Board

- for the purposes of evaluating and managing the prototype agreement, or in the view of the Board, a significant number of late returns of such information;
- (d) where the contractor has not continued to provide services under the prototype agreement to capitated patients for the duration of that prototype agreement as required under direction 15; or
- (e) where a breach notice has been issued to the contractor in accordance with paragraph 73 of Schedule 3 to the GDS Contracts Regulations (other contractual terms termination by the Board: remedial notices and breach notices) or paragraph 71 of Schedule 3 to the PDS Agreements Regulations (other contractual terms termination by the Board: remedial notices and breach notices).

Provisions relating to cessation of the Prototype Agreements Scheme and termination of a prototype agreement

- 11.—(1) The Board must co-operate with the participant and take the necessary steps that are reasonably required to ensure that the participant may—
 - (a) on the cessation of the Prototype Agreements Scheme; or
 - (b) on termination of a prototype agreement in accordance with direction 10,

and subject to paragraph (2), continue to provide primary dental services in accordance with the PDS agreement, or as the case may be, GDS contract.

- (2) Notwithstanding the provisions in paragraph (1), the Board, on cessation of the Prototype Agreements Scheme, or termination of the prototype agreement, must co-operate with the participant to ensure that the PDS agreement or, as the case may be, the GDS contract, continues to comply with the Act, any regulations made pursuant to the Act, or any directions given by the Secretary of State pursuant to the Act.
- (3) The terms and conditions of the prototype agreement do not override any obligations, rights, liabilities and duties which arise as a consequence of the terms and conditions of service which are required under the PDS Agreements Regulations and the GDS Contracts Regulations, except as expressly varied for the purposes of the Prototype Agreements Scheme.

Patient Information Leaflet

12. The participant must display in a prominent position in the participant's practice, in a part to which patients have access, the "NHS Dental Prototype Agreements – Patient Information" leaflet, published by the Department of Health(a), and must ensure that copies of this leaflet are made available to patients visiting the practice.

Records and information

- 13.—(1) The patient record must be kept in electronic form.
- (2) The participant must, to the Board, or at the request of the Board to a person authorised in writing by the Board, provide the information specified in paragraph (3).
 - (3) The information required under paragraph (2) is—
 - (a) costs of any appliances supplied or otherwise provided to patients receiving services under the PDS agreement or, as the case may be, the GDS contract; and
 - (b) details relating to laboratory costs associated with services provided under the PDS agreement or, as the case may be, the GDS contract.

⁽a) "NHS Dental Prototype Agreements – Patient Information" is available on www.gov.uk. A hard copy of this document can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS.

Dental Quality and Outcomes Framework

14. The participant must send the data required under the document entitled "Dental Quality and Outcomes Framework" published by the Department of Health (a).

Provision of treatment

15. In order to enable the Secretary of State to evaluate the prototype agreement, the contractor, if it commences to provide services to a patient under the Prototype Agreements Scheme, commits to continuing to providing such services to that patient for the duration of the prototype agreement.

Breach

16. The prototype agreement must provide that breach of the terms or the conditions specified in these Directions by the Board or the participant may lead to termination of the prototype agreement.

Interim care course of treatment

- 17.—(1) The additional advice and preventative treatment proposed for a patient in an interim care plan at a patient's oral health assessment or oral health review, known as an interim care course of treatment (within the meaning of the NHS Charges Regulations(b)), is to be provided by the participant as a new course of treatment.
- (2) All of the services proposed for a patient, and agreed with that patient, in the interim care plan must be provided to that patient in accordance with the prototype agreement.

Provisions relating to capitation and activity performance

- **18.**—(1) This direction applies to the overall capitation and activity performance level (as provided for in the Prototype $SFE(\mathbf{c})$), which the contractor is expected to achieve under the prototype agreement by the end of each financial year.
- (2) Where there is underperformance by the contractor that amounts to 4% or less (as calculated in accordance with paragraphs 4.8(a), 7.8(a), 20.8(a) and 23.8(a) of the Prototype SFE) of the level referred to in paragraph (1), the Board—
 - (a) must not take any action for breach of the prototype agreement (including termination of the prototype agreement); and
 - (b) may carry this amount over into the prototype agreement for the following financial year.
- (3) Where there has been over-performance by the contractor of 2% or less (as calculated in accordance with paragraphs 4.8(b), 7.8(b), 20.8(b) and 23.8(b) of the Prototype SFE), the Board may—
 - (a) carry over the amount into the following financial year; or
 - (b) pay the contractor an additional payment for the additional services provided.

Variation of capitation and dental activity

- **19.**—(1) Where the contractor or the Board is of the opinion that there needs to be a variation to the number of—
 - (a) units of dental activity; or

⁽a) The Dental Quality and Outcomes Framework is available on www.gov.uk. A hard copy of this document can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS.

⁽b) S.I. 2005/3477, as amended by S.I. 2006/1837, 2007/544, 2008/547, 2009/407, 2011/519, 2012/502, 2013/364 and 711, 2014/443 and 545 and 2015/417.

⁽c) See Sections 4, 7, 20 and 23 of the Prototype Agreements Scheme Statement of Financial Entitlements.

(b) capitated patients to whom the contractor is expected to have provided primary dental services by the end of the financial year,

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

- (2) The contractor or the Board must notify the other party to the prototype 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 must 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) capitated patients to whom the contractor is expected to have provided primary dental services by the end of the financial year,

and any related variations to the prototype agreement, including to the monies to be paid to the contractor under the prototype agreement, and must where appropriate effect the variation in accordance with paragraph 60 of Schedule 3 to the PDS Agreements Regulations (other contractual terms – variation of an agreement: general) and paragraph 60 of Schedule 3 to the GDS Contracts Regulations (other contractual terms – variation of a contract; general).

PART 3

Miscellaneous transitional provisions

Application of transitional provisions

20. This Part applies where a contractor who has held a Capitation and Quality Scheme 2 Agreement enters into a prototype agreement.

Continuity of forms

21. Any forms supplied by the Board in respect of the Capitation and Quality Scheme 2 continue to be valid for the purposes of the Prototype Agreements Scheme, until they are withdrawn or cancelled by the Board.

Transitional provision relating to notifications and agreements

- **22.**—(1) Notifications given to the Board, or by the Board to a participant of the Capitation and Quality Scheme 2 in respect of that scheme, or understandings reached between the Board and participants of the Capitation and Quality Scheme 2 are to be treated as notifications given to the Board, and by the Board, or understandings reached between the Board and the participants of the Prototype Agreements Scheme.
- (2) Notwithstanding this provision, the Board may request such further information as it needs, or review such understandings as it requires, but only to the extent that it considers just and necessary.

Transitional provision relating to continuity of care

23. Where a contractor who held a Capitation and Quality Scheme 2 Agreement enters into a prototype agreement, any treatment provided under the Capitation and Quality Scheme 2 continues under the prototype agreement.

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Signed	by author	ority of the	e Secretary	of State	tor He	alth

Peter Howitt
A member of the Senior Civil Service
Department of Health

23rd September 2015