#### NATIONAL ASSEMBLY FOR WALES

#### S U B O R D I N A T E L E G I S L A T I O N

#### 2007 No. 6

### NATIONAL HEALTH SERVICE ACT 1977

# The Local Health Board Dental Services Directions 2007

Made 30 January 2007

Coming into force 1 February 2007

The National Assembly for Wales, in exercise of the powers conferred by section 16BB(4) of the National Health Service Act 1977(1), hereby gives the following Directions:

### PART 1 GENERAL

### GENERALE

## Title, application, commencement and interpretation

1.—(1) The title of these Directions, is the Local Health Board Dental Services Directions 2007, which are given to Local Health Boards in Wales and which come into force on 1 February 2007.

(2) In these Directions—

"the 1977 Act" ("Deddf 1977") means the National Health Service Act 1977;

"additional services" ("gwasanaethau ychwanego") means one or more of—

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

#### (e) sedation services;

"advanced mandatory services" ("gwasanaethau gorfodol uwch") 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;

"child" ("plentyn") means a person who has not attained the age of 16 years;

"clinic" ("clinig") means a clinic established by a Local Health Board for the primary purpose of the provision of primary dental services under section 16CA(2) of the 1977 Act(1) (primary dental services):

"clinic premises" ("mangre'r clinig") means the premises or mobile clinic specified in the service statement;

"dental appliance" ("cyfarpar deintyddol") means a denture or bridge and for the purposes of this definition, a denture includes an obturator;

"dental care professional" ("proffesiynolyn gofal deintyddol") means a person whose name is included in the register of dental care professionals established under section 36B of the Dentists Act(2) (dental care professionals register);

"dental performers list" ("rhestr cyflawnwyr deintyddol") means a list of dental practitioners prepared in accordance with regulations made under section 28X of the 1977 Act(3) (persons performing primary medical and dental services);

"Dentists Act" ("Deddf Deintyddion") means the Dentists Act 1984(4);

<sup>(1)</sup> Section 16CA was inserted into the 1977 Act by section 170 of the Health and Social Care (Community Health and Standards) Act 2003 (c.43) ("the 2003 Act").

<sup>(2)</sup> Section 36B was inserted into the Dentists Act by article 29 of the Dentists Act 1984 (Amendment) Order 2005 (S.I. 2005/2011) ("the Dentists Act Order").

<sup>(3)</sup> Section 28X was inserted into the 1977 Act by section 179(1) of the 2003 Act.

<sup>(4) 1984 (</sup>c.24) amended by S.I 2001/3926 and 2005/2011.

"GDS Contracts Regulations" ("Rheoliadau Contractau GDS") means the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(1);

"health care professional" ("proffesiynolyn gofal iechyd") has the same meaning as in section 28M of the 1977 Act(2) (persons eligible to enter into GDS contracts);

"Local Health Board" ("Bwrdd Iechyd Lleol") unless the context otherwise requires, means the Local Health Board that has established the clinic;

"mandatory services" ("gwasanaethau gorfodol") means the services described in regulation 14 of the GDS Contracts Regulations;

"NHS Charge" ("ffi'r GIG") means a charge made to the patient for provision of services pursuant to the NHS Charges Regulations;

"NHS Charges Regulations" ("Rheoliadau Ffioedd y GIG") means the National Health Service (Dental Charges) (Wales) Regulations 2006(3);

"NHS Business Services Authority" ("Awdurdod Gwasanaethau Busnes y GIG") means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(4);

"normal clinic hours" ("oriau clinig arferol") means the times at which services will normally be provided by the clinic to patients and may be different for different services;

"orthodontic appliance" ("cyfarpar orthodontig") means a device used in the mouth to move or immobilise the teeth in order to correct or prevent malocclusion;

"patient" ("claf"), except where the context otherwise requires, means a person to whom the clinic is providing primary dental services under section 16CA(2) of the 1977 Act;

"prescriber" ("rhagnodydd") means a dental practitioner who is either engaged or employed by the Local Health Board; and

"service statement" ("datganiad gwasanaeth") means the statement prepared pursuant to direction 3.

<sup>(</sup>**1**) S.I. 2006/490 (W. 59).

<sup>(2)</sup> Section 28M was inserted into the 1977 Act by section 172(1) of the 2003 Act.

<sup>(3)</sup> S.I. 2006/491 (W. 60).

<sup>(</sup>**4**) S.I. 2005/2414.

## Primary dental services to be provided under section 16CA(2), 16CB or 28C of the 1977 Act only

**2.** No Local Health Board may provide primary dental services otherwise than under section 16CA(2), 16CB(1) (dental public health) or 28C(2) (personal medical or dental services) of the 1977 Act.

#### Service statement

- **3.**—(1) Where a Local Health Board wishes to provide primary dental services pursuant to section 16CA(2) of the 1977 Act (whether within or outside its area), it must establish one or more clinics for this purpose and must in respect of each clinic prepare a service statement which will set out—
  - (a) the mandatory or additional services to be provided;
  - (b) the address of each of the premises to be used for the provision of such services or in the case of the provision of services from a mobile clinic, that fact;
  - (c) to whom the clinic is to provide services, including, where appropriate, by reference to an area within which a person resident would be entitled to receive services from the clinic;
  - (d) the procedure (if any) by which a person may (except in the case of the provision of services in prisons and dental public health services) request services for himself or herself or on behalf of a person who requires such services;
  - (e) the circumstances in which and the procedure (if any) by which mandatory or additional services to a person can be refused or terminated; and
  - (f) such further details and requirements in relation to the administration and running of the clinic as the Local Health Board considers appropriate.
  - (2) The Local Health Board must ensure that—
    - (a) the clinic operates in accordance with the requirements and procedures specified in the service statement;
    - (b) the service statement is amended, as necessary, to reflect any changes to the matters specified in paragraph (1); and
    - (c) the clinic makes and recovers the NHS Charge in accordance with the NHS Charges Regulations.

<sup>(1)</sup> Section 16CB was inserted into the 1977 Act by section 171 of the 2003 Act

<sup>(2)</sup> Section 28C was inserted into the 1977 Act by section 21(1) of the National Health Service (Primary Care) Act 1997 (c.46).

- (3) A clinic may, in particular, consist of—
  - (a) one or more employees of the Local Health Board;
  - (b) one or more health care professionals providing services to the Local Health Board under a contract for services; or
  - (c) a combination of sub-paragraphs (a) and (b).

#### PROVISION OF SERVICES

#### Services to patients

- **4.** Where a clinic provides mandatory or additional services, the Local Health Board must ensure that the clinic—
  - (a) provides those services, and such other services that the service statement specifies, to the clinic's patients, during normal clinic hours to meet the reasonable needs of those patients; and
  - (b) provides details of the arrangements for dental services outside normal clinic hours to its patients and how to contact such services.

#### Premises, facilities and equipment

- **5.** The Local Health Board must ensure that the clinic premises, facilities and equipment used for the provision of primary dental services are—
  - (a) suitable for the delivery of those services; and
  - (b) sufficient to meet the reasonable needs of the clinic's patients.

#### PART 3

#### **PATIENTS**

#### Patient preference of practitioner

- **6.**—(1) Where a clinic provides mandatory or additional services, the Local Health Board must ensure (except in the case of the provision of services in a prison or dental public health services) that the clinic—
  - (a) informs 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, subject to paragraph (2), to express a preference to receive services from a particular performer; and

- (b) records in writing any such preference expressed by or on behalf of the patient.
- (2) The Local Health Board must ensure that the clinic endeavours to comply with any reasonable preference expressed under paragraph (1) but the clinic 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.

#### PRESCRIBING AND REFERRALS

#### **Prescribing - general**

- 7.—(1) The Local Health Board must ensure that a clinic complies with the requirements in directions 8 to 10 in respect of any prescription form for listed drugs, medicines or appliances issued by a prescriber.
- (2) The reference to a prescription form in this direction, direction 9(2) and direction 17 is to the form that is supplied by the Local Health Board for the purposes of direction 9(1).

#### Supply of drugs

- **8.**—(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 direction 9.
- (2) A prescriber may personally administer to a patient any drug or medicine required for the treatment of that patient.

#### **Issue of prescription forms**

- **9.**—(1) A prescriber must order listed drugs, medicines or appliances (other than those supplied in accordance with direction 8) as are needed for the treatment of any patient to whom it is providing services by issuing to the patient a prescription form.
  - (2) The prescription form must—
    - (a) be signed by the prescriber; and
    - (b) be issued separately to each patient to whom the clinic is providing services.

#### **Excessive prescribing**

**10.** A prescriber may 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 is reasonably necessary for the proper treatment of that patient.

#### Referral

- 11.—(1) Where a clinic does not provide the services a patient requires, the Local Health Board must ensure that the clinic, if the patient agrees, refers the patient in accordance with paragraph (2) to an alternative contractor, a hospital or other relevant service provider under Part 1 of the 1977 Act.
- (2) The Local Health Board must ensure that the clinic provides—
  - (a) to the patient referred, a referral notice on a form supplied for that purpose by the Local Health Board; and
  - (b) to the alternative contractor, hospital or other relevant service provider—
    - (i) a copy of the referral notice, and
    - (ii) a statement of the amount paid to the clinic, or due to be paid to the clinic, by the patient under the NHS Charges Regulations.

#### Inquiries in respect of referrals

- 12.—(1) The Local Health Board must ensure that the clinic sufficiently answer any inquiries whether oral or in writing from the NHS Business Services Authority concerning—
  - (a) the referral by or on behalf of the clinic of any patient for any other services provided under the 1977 Act; or
  - (b) the considerations by which the clinic makes such referrals or provides for them to be made on its behalf.
- (2) The clinic will not be obliged to answer any inquiry referred to in paragraph (1) unless it is made by an appropriately qualified dental practitioner(1), appointed by the NHS Business Services Authority to assist and the person produces, on request, written evidence that he or she is authorised by the NHS Business Services Authority to make such inquiry on its behalf.

<sup>(1)</sup> The term dental practitioner is defined in section 128 of the 1977 Act as a person registered in the dentists register under the Dentists Act.

#### PERSONS WHO PERFORM SERVICES

#### **Dental practitioners**

- **13.** The Local Health Board must ensure that no dental practitioner performs primary dental services in relation to a clinic unless he or she is—
  - (a) included in a dental performers list for a Local Health Board in Wales; and
  - (b) his or her inclusion in that list is not subject to a suspension.

#### **Dental care professionals**

- **14.**—(1) Prior to the coming into force of the first regulations under section 36A(2) of the Dentists Act(1) (professions complementary to dentistry), the Local Health Board must ensure that no—
  - (a) dental hygienist; or
  - (b) dental therapist,

performs primary dental services in relation to a clinic unless he or she is enrolled in the appropriate roll established in accordance with the Dental Auxiliaries Regulations 1986(2).

- (2) Upon the coming into force of the first regulations under section 36A(2) of the Dentists Act, the Local Health Board must ensure that no dental care professional performs primary dental services in relation to a clinic unless he or she is—
  - (a) included in the dental care professional register established under section 36B of the Dentists Act(3); and
  - (b) his or her registration in that register is not subject to a suspension.

#### Conditions for employment and engagement

- 15.—(1) Before employing or engaging any person to assist in the provision of primary dental services, the Local Health Board must take reasonable care to satisfy itself that the person in question is both suitably qualified and competent to discharge the duties for which he or she is to be employed or engaged.
- (2) When considering the competence and suitability of any person for the purpose of paragraph (1), the

<sup>(1)</sup> Section 36A is prospectively inserted into the Dentists Act by article 29 of the Dentists Act Order.

<sup>(2)</sup> S.I. 1986/887; relevant amending instruments are S.I. 1999/3460 and 2002/1671.

<sup>(3)</sup> Section 36B is prospectively inserted into the Dentists Act by article 29 of the Dentists Act Order.

Local Health Board must have regard, in particular, to—

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

#### **Training**

- **16.**—(1) The Local Health Board must ensure that for any dental practitioner or dental care professional, who is—
  - (a) performing dental services in a clinic; or
  - (b) employed or engaged to assist in the performance of such services,

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

- (2) The Local Health Board must ensure that it affords to each employee in the clinic reasonable opportunities to undertake appropriate training with a view to maintaining that employee's competence.
- (3) In paragraph (1), reference to dental care professional includes, until the coming into force of section 36B of the Dentists Act, dental therapists and dental hygienists included in the roll of such professions established by the General Dental Council.

#### Signing of documents

17.—(1) In addition to any other requirements relating to the documents specified in paragraph (2), whether in these directions or otherwise, the Local Health Board must ensure that the clinic secures that the

documents include—

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

#### INFORMATION, RECORDS, LEAFLETS AND GIFTS

#### **Patient information**

**18.** The Local Health Board must ensure that the clinic displays in a prominent position information relating to the NHS Charges made to the patient for provision of services pursuant to the NHS Charges Regulations.

#### Information in respect of services and treatment

- **19.**—(1) The Local Health Board must ensure that the clinic, 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) 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 of treatment not falling within sub-paragraph (d) or (e), treatment cannot be completed within a reasonable time,

sends to the NHS Business Services Authority, on a form supplied by the Local Health Board, the information specified in paragraph (2).

- (2) The information referred to in paragraph (1) comprises—
  - (a) details of the patient to whom the clinic 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.

#### Patient records

- **20.**—(1) The Local Health Board must ensure that the clinic keeps full, accurate and contemporaneous records in respect of the care and treatment of patients together with the documents referred to in paragraph (3).
- (2) Where a clinic provides mandatory or additional services, records of patients may be kept in electronic form.
  - (3) The documents referred to in paragraph (1) are—
    - (a) the written declaration form in respect of exemption under paragraph 1(1) of Schedule 12ZA to the 1977 Act(1) duly made and completed in accordance with regulations made under section 79 of, and paragraph 7(a) to, Schedule 12ZA to the 1977 Act;
    - (b) the note of the evidence in support of the declaration referred to in sub-paragraph (a); and
    - (c) the statement concerning any custom-made devices provided by any person as a consequence of regulation 15 of the Medical Devices Regulations 2002(2) (procedures for custom-made devices) in respect of services being provided.

#### Confidentiality of personal data

**21.** The Local Health Board must ensure that the clinic has a person who is responsible for practices and procedures relating to the confidentiality of personal data held by the clinic.

#### Patient information leaflet

- 22. Where a clinic provides mandatory services, the Local Health Board must ensure that there is in relation to that clinic a document (in this direction called a patient information leaflet) which will include the information specified in the Schedule and—
  - (a) which is reviewed at least once in every period of 12 months and amended as necessary to maintain its accuracy; and
  - (b) which is made available (including any subsequent updates), to the clinic's patients and prospective patients.

<sup>(1)</sup> Schedule 12ZA was inserted into the 1977 Act by section 183 of the 2003 Act.

<sup>(</sup>**2**) S.I. 2002/618.

#### **Gifts**

- 23.—(1) The Local Health Board must ensure that the clinic keeps a register of gifts which are given to any of the persons specified in 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 clinic,

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

- (2) The persons referred to in paragraph (1) are—
  - (a) the clinic;
  - (b) any person employed by the Local Health Board for the purposes of the clinic;
  - (c) any dental practitioner engaged by the Local Health Board for the purposes of the clinic;
  - (d) any spouse or civil partner of a person specified in sub-paragraphs (b) or (c); or
  - (e) any person whose relationship with a person specified in sub-paragraph (b) or (c) has the characteristics of the relationship between husband and wife or civil partners.
- (3) 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 clinic;
  - (b) the clinic is not aware of the gift; or
  - (c) the clinic is not aware that the donor wishes to provide services to the clinic.
- (4) The Local Health Board must ensure that the clinic takes reasonable steps to ensure that it is informed of gifts which fall within paragraph (1) and which are given to the persons specified in paragraph (2)(b) to (e).
- (5) The register referred to in paragraph (1) must 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 or her 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.

#### FEES AND CHARGES

#### Fees and charges

- **24.**—(1) The Local Health Board must ensure that the clinic, and any person performing primary dental services for the clinic, does not, either itself, himself or herself, or through any other person, demand or accept a fee or other remuneration, for its own or another's benefit from any patient of the clinic, for—
  - (a) the provision of any treatment under section 16CA(2) of the 1977 Act; or
  - (b) any prescription for any drug, medicine or appliance,

except in so far as the Local Health Board is entitled to charge for any such treatment or prescription by virtue of or under any enactment.

(2) The Local Health Board must ensure that the clinic and any other person performing primary dental services for the clinic will account for and pay to the Local Health Board, in such manner as it requires, the amount of any charges recovered from a patient in accordance with the NHS Charges Regulations.

#### **Evidence of exemption from charges**

- **25.** The Local Health Board must ensure that the clinic—
  - (a) requests, in respect of a person aged 18 years or over who makes a declaration relating to exemption under paragraph 1(1) of Schedule 12ZA to the 1977 Act, evidence in support of that declaration; and
  - (b) makes a note of the type of evidence submitted or, in the case where no evidence is submitted, a note of that fact is made.

Signed on behalf of the National Assembly for Wales

Date 30 January 2007

D Elis-Thomas

The Presiding Officer of the National Assembly

#### SCHEDULE 1 Direction 22

## INFORMATION TO BE INCLUDED IN A PATIENT INFORMATION

#### LEAFLET

A patient information leaflet must include—

- 1. The name of the Local Health Board.
- **2.** Whether the clinic undertakes the teaching or training of persons who provide or intend to provide dental services.
- **3.** Where services are, pursuant to the service statement, only to be provided to—
  - (a) persons resident in a particular area, the area (by reference to a sketch diagram, plan or postcode) within which a person resident would be entitled to receive services from the clinic:
  - (b) a specified group of persons, the particular services and a description of the group of persons to whom such services are to be provided.
- **4.** The clinic's telephone and fax number and its website address (if any).
- **5.** Whether the clinic's premises have suitable access for disabled patients and, if not, the alternative arrangements for providing services to such patients.
  - **6.** How to request services as a patient.
- **7.** The right of patients to express a preference of practitioner in accordance with direction 6 and the means of expressing such a preference.
  - **8.** The services available to patients.
- **9.** The opening days and hours of the clinic premises.
- **10.** The arrangements for services on the days and during the hours the clinic is not open (whether or not provided by the clinic) and how the patient may access such services.
- **11.** The telephone number of NHS Direct Wales and details of NHS Direct Wales online.
- **12.** How patients may make a complaint or comment on the provision of services.
- **13.** The rights and responsibilities of the patient, including keeping appointments.

- **14.** The action that may be taken where a patient is violent or abusive to any member of staff of the Local Health Board or other persons present on the clinic premises or in the place where treatment is provided by the clinic.
- **15.** 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.
- **16.** The fact that details of other primary dental services in the area may be obtained from the Local Health Board.