
WELSH STATUTORY INSTRUMENTS

2017 No. 202

The Private Dentistry (Wales) Regulations 2017

PART 1

General

Title and commencement

1. The title of these Regulations is the Private Dentistry (Wales) Regulations 2017 and they come into force on 1 April 2017.

Application

2. These Regulations apply in relation to Wales.

Interpretation

3.—(1) In these Regulations—

“the Act” (“*y Ddeddf*”) means the Care Standards Act 2000 and, with respect to Part 2 of that Act, means that Part as applied with modifications to private dental practices by the Care Standards Act 2000 (Extension of the Application of Part 2 to Private Dental Practices) (Wales) Regulations 2017(1) and by regulation 39 of these Regulations;

“the 1984 Act” (“*Deddf 1984*”) means the Dentists Act 1984(2);

“the 2005 Act” (“*Deddf 2005*”) means the Mental Capacity Act 2005(3);

“the 2008 Regulations” (“*Rheoliadau 2008*”) means the Private Dentistry (Wales) Regulations 2008(4);

“the 2011 Regulations” (“*Rheoliadau 2011*”) means the Private Dentistry (Wales) (Amendment) Regulations 2011(5);

“appropriate office of the registration authority” (“*swyddfa briodol yr awdurdod cofrestru*”) means in relation to a private dental practice—

(a) if an office has been specified under paragraph (2) for the area in which the private dental practice is situated, that office;

(b) in any other case, any office of the registration authority;

“dental care professional” (“*proffesiynolyn gofal deintyddol*”) means—

(a) a dental hygienist;

(b) a dental therapist; or

(1) S.I. 2017/200 (W.55).

(2) 1984 c. 24.

(3) 2005 c. 9. Relevant amendments were made by the Mental Health Act 2007 (c. 12), sections 50 and 55 and Part 10 of Schedule A1.

(4) S.I. 2008/1976 (W. 185).

(5) S.I. 2011/2686 (W. 288).

(c) a clinical dental technician;

“dental hygienist” (“*hylenydd deintyddol*”), “dental therapist” (“*therapydd deintyddol*”) and “clinical dental technician” (“*technegydd deintyddol clinigol*”) mean persons registered as such with the General Dental Council in the dental care professionals register established under section 36B of the 1984 Act;

“dental services” (“*gwasanaethau deintyddol*”) means dental care and treatment provided by a dentist;

“dentist” (“*deintydd*”) means a person registered in the dentists register kept in accordance with section 14 of the 1984 Act;

“domiciliary services” (“*gwasanaethau cartref*”) means a course of treatment, or part of a course of treatment, provided at a location other than—

- (a) the premises used to carry on a private dental practice;
- (b) a mobile surgery of any provider of private dental services;
- (c) a prison;

“exposure-prone procedures” (“*triniaethau a all arwain at gysylltiad*”) for the purposes of these Regulations refers to invasive procedures where there is a risk that injury to the dentist or dental care professional may result in the exposure of a patient’s open tissue to the blood of the dentist or dental care professional;

“health service hospital” (“*ysbyty gwasanaeth iechyd*”) has the same meaning as in section 206 of the National Health Service (Wales) Act 2006(6);

“insurance” (“*yswiriant*”) means—

- (a) a contract of insurance providing cover for liabilities which may be incurred in carrying out work as a dentist or dental care professional, or
- (b) an arrangement made for the purposes of indemnifying a person against such liabilities;

“major variation fee” (“*ffi amrywiad mawr*”) means the fee payable in respect of an application to vary a condition of registration where the registration authority considers it is necessary for them to inspect under Part 2 of the Act;

“minor variation fee” (“*ffi mân amrywiad*”) means the fee payable in respect of an application to vary a condition of registration where the registration authority considers it is not necessary for them to inspect under Part 2 of the Act;

“mobile surgery” (“*deintyddfa symudol*”) means, for the purposes of these Regulations, any vehicle in which private dental services are provided;

“organisation” (“*sefydliad*”) means a body corporate or any unincorporated association other than a partnership;

“patient” (“*claf*”) means a person to whom dental services or relevant professional services are provided;

“private dental practice” (“*practis deintyddol preifat*”) means an undertaking which consists of or includes the provision of—

- (a) private dental services; or
- (b) relevant professional services otherwise than for the purposes of the National Health Services (Wales) Act 2006;

“private dental services” (“*gwasanaethau deintyddol preifat*”) means dental services otherwise than for the purposes of the National Health Service (Wales) Act 2006 and “private dentistry” (“*deintyddiaeth breifat*”) is to be construed accordingly;

“reasonable adjustments” (“*addasiadau rhesymol*”) means such reasonable adjustments as would be required under the Equality Act 2010(7);

“registered manager” (“*rheolwr cofrestredig*”) means a person who is registered under Part 2 of the Act as the manager of a private dental practice;

“registered person” (“*person cofrestredig*”) means a person who is the registered provider or the registered manager of a private dental practice;

“registered provider” (“*darparwr cofrestredig*”) means a person who is registered under Part 2 of the Act as the person carrying on a private dental practice;

“relevant professional services” (“*gwasanaethau proffesiynol perthnasol*”) means the provision of professional services in accordance with the full scope of practice of a dental care professional, otherwise than in accordance with a prescription from a dentist but does not include—

- (a) the provision of tooth whitening services by a dental hygienist or a dental therapist, and
- (b) the provision and maintenance of dentures for dentate patients(8) by a clinical dental technician;

“responsible individual” (“*unigolyn cyfrifol*”) means an individual who is the director, manager, secretary or other officer of the organisation and is responsible for supervising the management of a private dental practice;

“scope of practice” (“*cwmpas ymarfer*”) has the meaning given for dentists and dental care professionals in the guidance on scope of practice published by the General Dental Council from time to time;

“statement of purpose” (“*datganiad o ddiben*”) means the statement compiled in accordance with regulation 5(1).

(2) The registration authority may specify an office controlled by it as the appropriate office in relation to private dental practices situated in a particular area of Wales.

(3) Where a person is acting on behalf of a patient (including where the patient is a child or lacks capacity) for the purposes of these Regulations and where the context requires, “a patient” (“*claf*”) also means the person acting on behalf of the patient.

Exceptions

4. For the purposes of these Regulations, an undertaking is not a private dental practice if it consists of—

- (a) the provision of private dental services by a dentist who is employed in a health service hospital and provides such services only in that hospital; or
- (b) the provision of private dental services by a dentist or relevant professional services by a dental care professional only in and for the purposes of an independent hospital.

Statement of purpose

5.—(1) The registered person must compile in relation to the private dental practice a statement on paper (“the statement of purpose”) which includes the matters listed in Schedule 1.

(2) The registered person must provide a copy of the statement of purpose to the appropriate office of the registration authority, post it on the website of the private dental practice (if there is a website) and make a copy of it available as soon as practicable on request by a patient.

(7) 2010 c. 15.

(8) A clinical dental technician may only provide the full range of services via direct access arrangements for edentulous patients.

(3) Subject to paragraph (4), the registered person must ensure that the private dental practice is conducted in a manner which is consistent with its statement of purpose.

(4) Nothing in paragraph (3), regulation 13(1) or 22(1) and (2) requires or authorises the registered person to contravene, or not comply with—

- (a) any other provision of these Regulations; or
- (b) the conditions for the time being in force in relation to the registration of the registered person under Part 2 of the Act.

Patient information

6.—(1) The registered person must compile a document (“the patient information leaflet”), which must include the information specified in Schedule 2.

(2) The registered person must provide a copy of the patient information leaflet to the appropriate office of the registration authority, post it on the website of the private dental practice (if there is a website) and make a copy of it available as soon as practicable on request by a patient.

(3) The registered person must ensure that there is displayed in a prominent position in the private dental practice, in a part to which patients have access, indicative information on charges payable by patients.

Review of the statement of purpose and patient information leaflet

7. The registered person must—

- (a) review the statement of purpose and patient information leaflet at least once in every period of twelve months and make any amendment necessary to maintain their accuracy; and
- (b) notify the appropriate office of the registration authority of any such amendment within 28 days of the review.

Policies and procedures

8.—(1) The registered person must prepare and implement written statements of the policies to be applied and the procedures to be followed in or for the purposes of a private dental practice in relation to each of the matters specified below—

- (a) the arrangements for acceptance of patients;
- (b) the arrangements for assessment, diagnosis and treatment of patients;
- (c) ensuring that the premises used for the purpose of carrying on the private dental practice are at all times fit for that purpose;
- (d) monitoring the quality and suitability of facilities and equipment, including maintenance of such equipment;
- (e) identifying, assessing and managing risks associated with the operation of the private dental practice to employees, patients, visitors and those working in or for the purposes of the private dental practice, including the steps taken in relation to regulation 13(5) and (6);
- (f) the creation, management, handling and storage of records and other information;
- (g) the provision of information to patients and others including clear notifications to patients of any charges payable for private dental services;
- (h) the recruitment, induction and retention of employees, their employment conditions and training requirements;
- (i) ensuring safe recruitment of staff including undertaking checks appropriate to the work that staff are to undertake;

- (j) ensuring that, where research is carried out in a private dental practice, it is carried out with the consent of any patient or patients involved, is appropriate for the practice concerned and is conducted in accordance with any up-to-date and authoritative published guidance on the conduct of research projects;
 - (k) the arrangements for ensuring the health and safety of staff and patients;
 - (l) the ordering, recording, administration and supply of medicines to patients;
 - (m) the arrangements relating to infection control including hand hygiene, safe handling and disposal of clinical waste, housekeeping and cleaning regimes and relevant training and advice;
 - (n) the arrangements for clinical audit;
 - (o) the arrangements for emergency contingencies which ensure the continuous safe running of the private dental practice;
 - (p) the provision of domiciliary services if such services are provided; and
 - (q) the arrangements for dealing with medical emergencies which ensure that staff who may be involved in dealing with a medical emergency receive appropriate training.
- (2) The policies and procedures referred to in paragraph (1) must be prepared having regard to the size of the private dental practice, the statement of purpose and the number and needs of the patients.
- (3) The registered person must prepare and implement written statements of policies to be applied and procedures to be followed for the care and treatment of patients who lack capacity within the meaning of the 2005 Act, which accord with the 2005 Act and any relevant Code of Practice and guidance.
- (4) The written statements referred to in paragraph (3) must include policies and procedures which ensure that—
- (a) the capacity of each patient to consent to treatment is assessed;
 - (b) in the case of a patient who lacks capacity, the requirements of the 2005 Act are complied with before any treatment proposed for the patient is administered; and
 - (c) information about the health, care and treatment of a patient who lacks capacity is disclosed only to those persons who need to be aware of that information in order to treat the patient effectively or minimise any risk of the patient harming himself or herself or another person.
- (5) Where domiciliary services are provided by the private dental practice, the registered person must—
- (a) prepare and implement written statements of policies to be applied and procedures to be followed for the provision of domiciliary services; and
 - (b) have regard to any national guidance on the provision of domiciliary services when preparing the written statements referred to in sub-paragraph (a).
- (6) The registered person must review the operation of policies and procedures implemented under this regulation and regulation 21 (complaints) at intervals of not more than three years and, where appropriate, revise and implement those policies and procedures.
- (7) The registered person must make available upon request by a patient, and any prospective patient, copies of the policies and procedures.
- (8) The registered person must retain copies of all policies and procedures referred in this regulation, including previous versions of policies and procedures that have been revised in accordance with paragraph (6), for a period of not less than three years from the date of creation or revision of the policy or procedure.
- (9) The registered person must make a copy of all written statements prepared in accordance with this regulation available for inspection by the registration authority.

PART 2

Registered Persons

Fitness of registered provider

- 9.**—(1) A person must not carry on a private dental practice unless the person is fit to do so.
- (2) A person is not fit to carry on a private dental practice unless the person—
- (a) is an individual who satisfies the requirements set out in paragraph (3);
 - (b) is a partnership, and each of the partners satisfies the requirements in paragraph (3); or
 - (c) is an organisation and—
 - (i) the organisation has given notice to the appropriate office of the registration authority of the name, address and position in the organisation of the responsible individual; and
 - (ii) that individual satisfies the requirements in paragraph (3).
- (3) The requirements are that—
- (a) the individual is of suitable integrity and good character to carry on, or, as the case may be, be responsible for the supervision of the management of, the private dental practice;
 - (b) the individual is able by reason of their health, after reasonable adjustments (if any) are made, to carry on, or as the case may be, be responsible for the supervision of the management of, the private dental practice; and
 - (c) full and satisfactory information or documentation, as the case may be, is available in relation to the individual in respect of each of the matters specified in Part 1 of Schedule 3.
- (4) In assessing an individual’s character for the purposes of paragraph (3)(a), the matters considered must include those listed in Part 2 of Schedule 3.
- (5) A person is not fit to carry on a private dental practice if that person has—
- (a) been adjudged bankrupt⁽⁹⁾ or sequestration of the person’s estate has been awarded and (in either case) the person has not been discharged and the bankruptcy order⁽¹⁰⁾ has not been annulled or rescinded or a moratorium period under a debt relief order (within the meaning of section 251A of the Insolvency Act 1986)⁽¹¹⁾ applies in relation to the person; or
 - (b) made a composition or arrangement with the person’s creditors and has not been discharged in respect of it.

Appointment of manager

- 10.**—(1) The registered provider must appoint an individual to manage the private dental practice if the registered provider—
- (a) is an organisation or a partnership;
 - (b) is not a fit person to manage the private dental practice; or
 - (c) is not, or does not intend to be, in full-time day to day charge of the private dental practice.
- (2) If the registered provider appoints an individual to manage the private dental practice, the registered provider must immediately give notice to the appropriate office of the registration authority of the name of the individual appointed and the date on which the appointment takes effect.

⁽⁹⁾ See section 381(1) of the Insolvency Act 1986 for the meaning of “bankrupt”.

⁽¹⁰⁾ See section 381(2) of the Insolvency Act 1986 for the meaning of “bankruptcy order”.

⁽¹¹⁾ 1986 c. 45. Section 251A was inserted by section 108 of and Schedule 17 to the Tribunals, Courts and Enforcement Act 2007 (c. 15).

Fitness of manager

- 11.**—(1) A person must not manage a private dental practice unless the person is fit to do so.
- (2) A person is not fit to manage a private dental practice unless—
- (a) the person is of suitable integrity and good character to manage the private dental practice; and
 - (b) having regard to the size of the private dental practice, the statement of purpose and the number and needs of the patients—
 - (i) the person has the qualifications, skills and experience necessary to manage the private dental practice; and
 - (ii) the person is able by reason of their health, after reasonable adjustments (if any) are made, to do so; and
 - (iii) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in Part 1 of Schedule 3.
- (3) In assessing a person’s character for the purposes of paragraph (2)(a), the matters considered must include those listed in Part 2 of Schedule 3.
- (4) Where a person manages more than one private dental practice, that person must spend sufficient time at each practice to ensure that the practice is managed effectively.

Registered person – general requirements and training

- 12.**—(1) The registered provider and the registered manager must, having regard to the size of the private dental practice, the statement of purpose and the number and needs of the patients, carry on or manage the private dental practice, as the case may be, with sufficient care, competence and skill.
- (2) The registered provider and the registered manager must undertake, from time to time, such training as is appropriate to ensure that they have the skills necessary to carry on or manage the private dental practice, as the case may be.
- (3) For the purposes of this regulation, the training referred to in paragraph (2) must be undertaken by—
- (a) the individual, if the registered provider is an individual;
 - (b) the responsible individual, if the registered provider is an organisation; or
 - (c) one of the partners, if the registered provider is a partnership.

PART 3

Conduct of Private Dental Practice

CHAPTER 1

Quality of Service Provision

Quality of treatment and other service provision

- 13.**—(1) Subject to regulation 5(4) (statement of purpose), the registered person must provide any treatment and other services to patients in accordance with the statement of purpose, and must ensure that any treatment and other services provided to each patient—
- (a) meet the patient’s individual needs; and

- (b) ensure the welfare and safety of the patient.
- (2) The registered person must ensure that—
 - (a) all equipment used in or for the purposes of the private dental practice is safe and in good condition and suitable for the purpose for which it is to be used; and
 - (b) staff are adequately trained to use any equipment (including medical devices and diagnostic systems) that they are required to use in or for the purposes of the private dental practice.
- (3) Where reusable medical devices are used in a private dental practice, the registered person must ensure that—
 - (a) such devices are handled safely;
 - (b) appropriate procedures are implemented in relation to cleaning, disinfection, inspection, packaging, sterilisation, transportation and storage of such devices; and
 - (c) appropriate arrangements are in place for promptly dealing with any device or system failure.
- (4) The registered person must protect patients against the risks associated with the unsafe use and management of medicines, by—
 - (a) making appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used in or for the purposes of the private dental practice;
 - (b) having regard to any guidance issued by the registration authority or appropriate expert body in relation to the safe handling and use of medicines;
 - (c) ensuring that dentists and dental care professionals are qualified and trained in prescribing and administering medicines within their scope of practice;
 - (d) ensuring that patients and staff have access to advice and information on medicines used in or for the purposes of the private dental practice; and
 - (e) ensuring that all drug-related adverse incidents are reported.
- (5) The registered person must, so far as reasonably practicable, ensure that the following persons are protected against identifiable risks of acquiring a health care-associated infection by the means specified in paragraph (6)—
 - (a) patients; and
 - (b) others who may be at risk of exposure to such an infection arising from working in or for the purposes of a private dental practice.
- (6) The means referred to in paragraph (5) are—
 - (a) the effective operation of systems designed to assess the risk of and to prevent, detect and control the spread of a health care-associated infection;
 - (b) the maintenance of appropriate standards of cleanliness and hygiene in relation to—
 - (i) premises used for the purpose of carrying on the private dental practice;
 - (ii) equipment and reusable medical devices used for the purpose of carrying on the private dental practice; and
 - (iii) materials to be used in the treatment of service users where such materials are at risk of being contaminated; and
 - (c) ensuring that an effective system is implemented for ensuring that all staff have successfully completed—
 - (i) standard health checks; and

(ii) additional health checks where staff will be performing exposure-prone procedures.

(7) The registered person must have regard to current guidance published by the Welsh Ministers⁽¹²⁾ when implementing the system referred to in paragraph (6)(c).

(8) The registered person must take account of any advice relating to the type of treatment the private dental practice provides and to patient safety information published by recognised regulatory, professional or statutory expert bodies.

(9) The registered person must ensure that—

- (a) patients are provided with timely and accessible information on their condition, care, medication, treatment and support arrangements;
- (b) patients are provided with opportunities to discuss and agree options available in relation to their medication (if any), treatment and support;
- (c) patient information is treated confidentially; and
- (d) valid consent is given to treatment.

Safeguarding patients

14.—(1) The registered person must make suitable arrangements to ensure that patients are safeguarded against the risk of abuse and improper treatment by—

- (a) ensuring that staff are made aware of the need to safeguard children and adults at risk⁽¹³⁾ and are familiar with any national procedures for the protection of children and adults at risk;
- (b) ensuring that staff are appropriately trained in safeguarding issues including the protection of children and adults at risk;
- (c) ensuring that staff are aware of who to contact locally in the event of a concern relating to the protection of children and adults at risk;
- (d) taking reasonable steps to identify the possibility of abuse and responding appropriately to any allegations of abuse; and
- (e) ensuring that staff have access to support and up-to-date guidance in the event of a concern about the welfare and safety of a child or adult at risk.

(2) When making the arrangements referred to in paragraph (1), the registered person must have regard to any guidance issued by the registration authority or appropriate expert body in relation to the protection of children and adults at risk.

Privacy, dignity and relationships

15.—(1) The registered person must make suitable arrangements to ensure that the private dental practice is conducted in a manner which respects the privacy and dignity of patients.

(2) When making the arrangements referred to in paragraph (1), the registered person must have regard to the protected characteristics set out in the Equality Act 2010⁽¹⁴⁾.

(3) The registered provider and the registered manager (if any) must take all reasonable steps to ensure that the private dental practice is conducted on the basis of good personal and professional relationships—

- (a) between each other;

⁽¹²⁾ Guidance on health clearance for health workers is currently set out in the Welsh Health Circular WHC (2006) 86 published by the Welsh Government. This guidance is subject to amendment.

⁽¹³⁾ “Adults at risk” has the same meaning as in section 126(1) of the Social Services and Well-being (Wales) Act 2014 (anaw 4).

⁽¹⁴⁾ 2010 c. 15. The protected characteristics are set out in Chapter 1 of Part 2 of the Equality Act 2010.

- (b) between them and the staff members; and
- (c) between all those employed in or for the purposes of the private dental practice and the patients.

Assessing and monitoring the quality of service provision including annual returns

16.—(1) The registered person must—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the practice against the requirements set out in these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of staff and patients.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
 - (i) the information contained in the records referred to in regulation 20 (records);
 - (ii) the comments and complaints made, and views (including the descriptions of their experiences of care and treatment) expressed by patients pursuant to subparagraph (c) and regulation 21 (complaints);
 - (iii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the private dental practice; and
 - (iv) reports prepared by the registration authority from time to time pursuant to section 32(5) of the Act (inspections: supplementary) in relation to the private dental practice;
- (c) regularly seek the views (including the descriptions of their experiences of care and treatment) of patients and persons who are employed in or for the purposes of the private dental practice; and
- (d) where necessary, make changes to the service delivery, treatment or care provided in order to reflect—
 - (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a patient;
 - (ii) the conclusions of local and national service reviews, clinical audits and research carried out by appropriate expert bodies; and
 - (iii) the views of patients and persons who are employed in or for the purposes of the private dental practice.

(3) The registered person must send to the appropriate office of the registration authority, when requested to do so, an annual return setting out how the registered person has met the requirements of paragraph (1), together with any plans that the registered person has for improving the standard of the services, treatment and care provided to patients with a view to ensuring their health, welfare and safety.

(4) The registered person must take reasonable steps to ensure that the annual return is not misleading or inaccurate.

(5) The registered person must supply the annual return to the appropriate office of the registration authority within the time frame stipulated by the authority.

Staffing

17.—(1) The registered person must, having regard to the nature of the private dental practice, the statement of purpose and the number and needs of patients—

- (a) ensure that at all times suitably qualified, skilled and experienced persons are working in or for the purposes of the private dental practice in such numbers as are appropriate for the health, welfare and safety of the patients; and
- (b) ensure that the employment of any persons on a temporary basis in or for the purposes of the private dental practice will not prevent patients from receiving such continuity of care as is reasonable to meet their needs.

(2) The registered person must ensure that each dentist or dental care professional working in or for the purposes of the private dental practice is registered with the General Dental Council.

(3) The registered person must ensure that each person employed in or for the purposes of the private dental practice—

- (a) receives appropriate training and supervision;
- (b) is enabled from time to time to obtain further training appropriate to their role;
- (c) is provided with a job description outlining the person's responsibilities;
- (d) has a written contract; and
- (e) has access to processes which enable them to raise, in confidence and without prejudice to their employment, concerns over any aspect of service delivery, treatment or management.

(4) The registered person must ensure that each person employed in or for the purposes of the private dental practice receives regular and appropriate appraisals and must take such steps as may be necessary to address any aspect of—

- (a) a dentist or dental care professional's clinical practice; or
- (b) the performance of a member of staff who is not a dentist or dental care professional,

which is found to be unsatisfactory.

(5) The registered person must take reasonable steps to ensure that any persons working in or for the purposes of the private dental practice who are not employed by the registered person and to whom paragraph (3) does not apply are appropriately supervised while carrying out their duties to ensure patients' health, welfare and safety are not compromised.

Fitness of workers

18.—(1) The registered person must not—

- (a) employ under a contract of employment a person to work in or for the purposes of a private dental practice unless that person is fit to do so; or
- (b) allow any other person to work in or for the purposes of a private dental practice unless that person is fit to do so.

(2) For the purposes of paragraph (1) a person is not fit to work in or for the purposes of the private dental practice unless—

- (a) the person is registered with the General Dental Council, if they are required to do so;
- (b) the person is of suitable integrity and good character;
- (c) the person has the qualifications, skills and experience which are necessary for the work which that person is to perform;
- (d) the person is able, by reason of their health, after reasonable adjustments (if any) are made, of properly performing tasks which are intrinsic to that work; and

(e) full and satisfactory information or documentation, as the case may be, is available in relation to the person in respect of each of the matters specified in Part 1 of Schedule 3.

(3) In assessing an individual's character for the purposes of paragraph (2)(b), the matters considered must include those listed in Part 2 of Schedule 3.

Guidance for dentists and dental care professionals

19. The registered person must ensure that any code of ethics or professional practice prepared by the General Dental Council is made available in the private dental practice.

Records

20.—(1) The registered person must ensure that a comprehensive dental care record which may be in paper or electronic form is maintained in relation to each patient—

(a) which includes—

(i) a contemporaneous and accurate note of all assessment, treatment planning and treatment provided to the patient; and

(ii) the patient's dental and any relevant medical history and all other notes prepared by a dentist or dental care professional about the patient's case; and

(b) the record is retained for a minimum period of eight years beginning on the date on which the treatment which the record refers was concluded or terminated.

(2) The registered person must ensure that—

(a) the dental care record for a person who is currently a patient is kept in a secure place in the premises used to carry on the private dental practice; and

(b) the dental care record for a person who is no longer a patient is stored securely (whether in the practice or elsewhere) and that it can be located if required.

(3) Where a private dental practice ceases to operate the registered person must ensure that the records maintained in accordance with paragraph (1) are kept securely elsewhere and must make them available for inspection by the registration authority at its request.

Complaints

21.—(1) The registered person must establish and operate effectively a clear and accessible procedure ("the complaints procedure") for considering and responding to complaints made to the registered person by a patient.

(2) The registered person must—

(a) ensure that any complaint made under the complaints procedure is investigated;

(b) ensure that necessary and proportionate action is taken in response to any failure identified by the complaint or investigation; and

(c) in operating the complaints procedure, take account of the ascertainable wishes and feelings of the patient and respect the patient's privacy as far as possible.

(3) The registered person must supply a written copy of the complaints procedure upon request to a patient and any prospective patient.

(4) The written copy of the complaints procedure must include—

(a) the name, address and telephone number of the registration authority; and

(b) the procedure (if any) which has been notified by the registration authority to the registered person for making complaints to the registration authority relating to the private dental practice.

(5) The registered person must maintain a record of each complaint, including details of the investigations made, the outcome and any action taken in consequence, including whether any action is necessary to improve the quality of treatment or services.

(6) The registered person must supply to the registration authority at its request, and by no later than 28 days beginning on the date after receipt of the request, copies of records maintained under paragraph (5).

CHAPTER 2

Premises

Fitness of premises

22.—(1) The registered person must not use premises to carry on a private dental practice unless those premises are of a physical design and layout which are suitable for the purpose of achieving the aims and objectives set out in the statement of purpose.

(2) The registered person must ensure that—

- (a) the premises provide a clean, safe and secure environment;
- (b) the premises are of sound construction and kept in a good state of repair externally and internally; and
- (c) the size and layout of the premises are suitable for the purposes for which they are used and are suitably equipped and furnished.

(3) The registered person must provide for employees—

- (a) facilities for the purposes of changing; and
- (b) storage facilities.

(4) Subject to paragraph (5) the registered person must—

- (a) take adequate precautions against the risk of fire, including the provision and maintenance of adequate fire prevention and detection equipment;
- (b) provide adequate means of escape in the event of a fire;
- (c) make arrangements for persons employed in the private dental practice to receive suitable training in fire prevention;
- (d) ensure, by means of fire drills and practices at suitable intervals, that employees of the private dental practice are aware of the procedure to be followed in case of fire;
- (e) review fire precautions, the suitability of fire equipment and the procedure to be followed in case of fire at intervals not exceeding twelve months; and
- (f) produce and maintain a written fire safety risk assessment.

(5) Where the Regulatory Reform (Fire Safety) Order 2005(15) applies to the private dental practice—

- (a) paragraph (4) does not apply; and
- (b) the registered person must ensure that the requirements of that Order, and any regulations made under it, except for article 23 (general duties of employees at work), are complied with in respect of the premises used for the purpose of providing private dental services.

CHAPTER 3

Management

Visits by registered provider to private dental practice

23.—(1) Where the registered provider is an individual who does not manage the private dental practice, that individual must visit the premises used to carry on the private dental practice in accordance with this regulation.

(2) Where the registered provider is an organisation or a partnership, the premises used to carry on the private dental practice must be visited in accordance with this regulation by—

- (a) the responsible individual;
- (b) another of the directors or, as the case may be, partners, or other persons responsible for the management of the organisation or partnership; or
- (c) an employee of the organisation who has appropriate qualifications, skills and experience for the purpose and who is not directly concerned with the conduct of the private dental practice.

(3) Visits under paragraph (1) or (2) must take place at least every twelve months and may be unannounced.

(4) The person carrying out the visit must—

- (a) interview such employees as appear to be necessary in order to form an opinion of the standard of care, treatment and other services provided in or for the purposes of the private dental practice;
- (b) inspect the premises used to carry on the private dental practice and records of any complaints; and
- (c) prepare a written report on the conduct of the private dental practice.

(5) The registered provider must supply a copy of the report required to be made under paragraph (4)(c) to—

- (a) the registered manager; and
- (b) in the case of a visit under paragraph (2)—
 - (i) where the registered provider is an organisation, to each of the directors or other persons responsible for the management of the organisation;
 - (ii) where the registered provider is a partnership, to each of the partners.

(6) The registered provider must, if the registration authority so requests, supply it with a copy of the report required to be made under paragraph (4)(c).

Financial position

24. The registered person must take all reasonable steps to carry on the private dental practice in such a manner as is likely to ensure that it will be financially viable for the purpose of achieving the aims and objectives set out in its statement of purpose.

CHAPTER 4

Notices to be Given to the Registration Authority

Notification of events

25.—(1) The registered person must give notice to the appropriate office of the registration authority, as soon as it is practicable to do so, of—

- (a) the death of, or any serious injury to, a patient—
 - (i) during treatment provided in or for the purposes of the private dental practice;
 - (ii) as a consequence of treatment provided in the private dental practice; or
 - (iii) otherwise on the premises of the private dental practice;
 - (b) the outbreak of any infectious disease which in the opinion of any dentist or dental care professional working in the practice is sufficiently serious to be so notified; or
 - (c) any allegation of misconduct resulting in actual or potential harm to a patient by the registered person or any person employed in or for the purposes of the private dental practice.
- (2) In the case of the death of a patient, the registered person must also notify the registration authority of the date, time, cause (where known) and circumstances of the patient's death.
- (3) The registered person must keep a secure written record of all events listed in sub-paragraphs (a) to (c) of paragraph (1).

Notice of temporary absence of registered person

26.—(1) Where—

- (a) a registered provider who manages the private dental practice; or
- (b) a registered manager,

proposes to be absent from the private dental practice for a continuous period of 28 days or more, the registered person must give notice in writing to the appropriate office of the registration authority.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) must be given no later than one month before the proposed absence commences or within such shorter period as may be agreed with the registration authority and the notice must specify with respect to the absence—

- (a) its length or expected length;
- (b) the reason for it;
- (c) the arrangements which have been made for running the private dental practice;
- (d) the name, address and qualifications of the person who will be responsible for the private dental practice during that absence; and
- (e) the arrangements that have been or are proposed to be made for appointing another person to manage the private dental practice during that absence, including the proposed date by which the appointment is to be made.

(3) Where the absence arises as a result of an emergency, the registered person must give notice of the absence within one week of the emergency's occurrence, specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(4) Where—

- (a) a registered provider who manages the private dental practice; or
- (b) a registered manager,

has been absent from the private dental practice for a continuous period of 90 days or more, and the appropriate office of the registration authority has not been given notice of the absence, the registered person must give notice in writing to that office, as soon as it is practicable to do so, specifying the matters set out in sub-paragraphs (a) to (e) of paragraph (2).

(5) The registered person must notify the appropriate office of the registration authority of the return to work of a person mentioned in sub-paragraph (a) or (b) of paragraph (4) not later than 7 days after the date of that person's return to work.

Notice of changes

27.—(1) The registered person must give notice in writing to the appropriate office of the registration authority, as soon as it is practicable to do so, if any of the following events take place or are proposed to take place—

- (a) a person other than the registered person carries on or manages the private dental practice;
- (b) a person ceases to carry on or manage the private dental practice;
- (c) where the registered person is an individual, that individual changes their name;
- (d) where the registered provider is a partnership, there is any change in the membership of the partnership;
- (e) where the registered provider is an organisation—
 - (i) the name or address of the organisation is changed;
 - (ii) there is any change of director, manager, secretary or other similar officer of the organisation;
- (f) the responsible individual changes their name;
- (g) there is any change in the identity of the responsible individual;
- (h) where the registered provider is an individual, a trustee in bankruptcy is appointed or a composition or arrangement is made with creditors;
- (i) where the registered provider is a company or partnership, a receiver, manager, liquidator or provisional liquidator is appointed; or
- (j) the premises used to carry on the private dental practice are significantly altered or extended, or additional premises are acquired which are intended to be used for the purposes of the practice.

Notification of offences

28. Where the registered person or the responsible individual is convicted of any criminal offence, whether in Wales or elsewhere, the person convicted must immediately give notice in writing to the appropriate office of the registration authority of—

- (a) the date and place of the conviction;
- (b) the offence of which the person was convicted; and
- (c) the penalty imposed on the person in respect of the offence.

Appointment of liquidators etc.

29.—(1) Any person to whom paragraph (2) applies must—

- (a) give notice in writing to the appropriate office of the registration authority of the person's appointment indicating the reasons for it;
- (b) appoint a manager to take full-time day to day charge of the private dental practice in any case where the duty under regulation 10(1) is not being met; and
- (c) before the end of the period of 28 days beginning on the date of the person's appointment, notify the appropriate office of the registration authority of the person's intentions regarding the future operation of the private dental practice to which the appointment relates.

(2) This paragraph applies to any person appointed as—

- (a) the receiver or manager of the property of an organisation which is a registered provider of a private dental practice;

- (b) a liquidator or provisional liquidator of a company which is the registered provider of a private dental practice;
- (c) the trustee in bankruptcy of a registered provider of a private dental practice.

Death of a registered person

30.—(1) If more than one person is registered in respect of a private dental practice, and a registered person dies, any surviving registered person must give notice of the death in writing to the appropriate office of the registration authority, as soon as it is practicable to do so.

(2) If only one person is registered in respect of a private dental practice, and the person dies, the person's personal representatives must—

- (a) give notice of the death in writing to the appropriate office of the registration authority, as soon as it is practicable to do so; and
- (b) give notice to that authority of their intentions regarding the future running of the private dental practice, within 28 days of the death.

(3) The personal representatives of the deceased registered provider may carry on the private dental practice without being registered in respect of it—

- (a) for a period not exceeding 28 days; and
- (b) for any further period as may be determined by the registration authority in accordance with paragraph (4).

(4) The registration authority may extend the period specified in paragraph (3)(a) by such further period, not exceeding six months, as the registration authority may determine, and must notify any such determination to the personal representatives in writing.

(5) The personal representatives must appoint a manager to take full-time day to day charge of the private dental practice during any period in which, in accordance with paragraph (3), they carry on the private dental practice without being registered in respect of it.

(6) The provisions of regulation 11 apply to a manager appointed in accordance with paragraph (5).

(7) Where the registration authority receives an application for registration as provider in respect of the private dental practice referred to in paragraph (1), the six months referred to in paragraph (4) may be extended by a period not exceeding six months as the registration authority may determine.

PART 4

Additional Requirements

Resuscitation

31.—(1) The registered person must prepare and implement a written statement, based on current national guidelines for resuscitation, of the policies to be applied and the procedures to be followed in the private dental practice in relation to resuscitation of patients and must review such statement annually.

(2) The registered person must ensure that the policies and procedures referred to in paragraph (1)

- (a) are available on request to every patient; and
- (b) are communicated to and understood by any person working in or for the purposes of the private dental practice who may be involved in decisions about resuscitation of a patient.

- (3) The registered person must also—
- (a) ensure that any person working in or for the purposes of the private dental practice who may be involved in decisions about resuscitation of a patient, or who may be involved in the resuscitation of patients, has been suitably trained; and
 - (b) ensure that all equipment and medicines necessary for the resuscitation of patients are available on the premises used to carry on the private dental practice.

Use of Class 3B or Class 4 laser product

32.—(1) The registered person must ensure that no Class 3B or Class 4 laser product⁽¹⁶⁾ is used in or for the purposes of the private dental practice unless the registered person has in place a professional protocol drawn up by a trained and experienced dentist or dental care professional in accordance with which treatment using a Class 3B or Class 4 laser product is to be provided, and that the treatment is provided in accordance with it.

(2) The registered person must maintain at the private dental practice a register of each occasion where a Class 3B or Class 4 laser product has been used which includes—

- (a) the name of the patient in connection with whose treatment the Class 3B or Class 4 laser product was used;
- (b) the name of the person who used the Class 3B or Class 4 laser product; and
- (c) the date on which it was used.

(3) The registered person must ensure that such a Class 3B or Class 4 laser product is used in the private dental practice only by a person who has undertaken appropriate training and has demonstrated an understanding of—

- (a) the correct use of the Class 3B or Class 4 laser product;
- (b) the risks associated with using the Class 3B or Class 4 laser product;
- (c) its biological and environmental effects;
- (d) precautions to be taken before and during use of a Class 3B or Class 4 laser product; and
- (e) action to be taken in the event of an accident, emergency or other adverse incident involving a Class 3B or Class 4 laser product.

PART 5

Miscellaneous

Fees

33. Schedule 5 specifies the fees that are payable by applicants for registration and registered persons under Part 2 of the Act.

34.—(1) Subject to paragraph (2), a dentist may request a refund of the annual fee prescribed in the 2008 Regulations if—

- (a) an application for registration under Part 2 of the Act has been made to the registration authority in respect of the private dental practice in which the dentist works;
- (b) the application for registration has been granted by the registration authority; and

⁽¹⁶⁾ For the meaning of Class 3B or Class 4 laser product *see* Part 1 of British Standard EN 60825 – 1 (Radiation safety of laser products and systems). Copies can be obtained from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.

- (c) the dentist paid an annual fee under the 2008 Regulations within the six months prior to the application for registration being granted.
- (2) A request for a refund made by a dentist described in paragraph (1) must be made within three months of the date on which the application for registration referred to in paragraph (1) was granted.
- (3) Where a dentist requests a refund in accordance with paragraph (2) and the registration authority agrees to grant the request, then a refund will be paid to the dentist on the basis of one twelfth of the annual fee paid for each complete month following the date on which the application for registration referred to in paragraph (1) was granted.
- (4) If a dentist works in more than one private dental practice, the dentist may only request a refund if—
- (a) an application for registration has been made to the registration authority in respect of each private dental practice in which the dentist works; and
 - (b) each application for registration has been granted.

Compliance with regulations

35. Where there is more than one registered person in respect of a private dental practice, anything which is required under these Regulations to be done by the registered person will, if done by one of the registered persons, not be required to be done by any of the other registered persons.

Offences

- 36.—**(1) A contravention, or failure to comply with any of the provisions of regulations 5 to 32, is an offence.
- (2) The registration authority may bring proceedings against a person who was once, but no longer is, a registered person, in respect of a failure to comply with regulation 20 (records) after the person ceased to be a registered person.

Amendments to the Independent Health Care (Wales) Regulations 2011

37. The Independent Health Care (Wales) Regulations 2011(17) are amended as follows.

38.—(1) In regulation 2(1) (interpretation) in the appropriate places insert—

““dental care professional” (“*proffesiynolyn gofal deintyddol*”) means—

- (a) a dental hygienist;
- (b) a dental therapist; or
- (c) a clinical dental technician;”;

““dental hygienist” (“*hyleneydd deintyddol*”), “dental therapist” (“*therapydd deintyddol*”) and “clinical dental technician” (“*technegydd deintyddol clinigol*”) mean persons registered as such with the General Dental Council in the dental care professional register established under section 36B of the Dentists Act 1984;”.

(2) In regulation 3 (meaning of “independent hospital”) after paragraph (2)(b) insert—

- “(ba) dental treatment using a Class 4 laser product where such treatment is carried out by or under the supervision of a dentist or dental care professional working in a private dental practice within the meaning of the Private Dentistry (Wales) Regulations 2017;”.

Application of Part 2 of the Act to persons carrying on or managing a private dental practice

39. The provisions of Part 2 of the Act, insofar as they apply to Wales and are not already applied by the Care Standards Act 2000 (Extension of the Application of Part 2 to Private Dental Practices) (Wales) Regulations 2017, apply to registered persons in accordance with the modifications set out in Schedule 4.

Transitional provisions

40.—(1) This paragraph applies to any person who—

- (a) carries on or manages a private dental practice which consists of or includes the provision of relevant professional services by a dental care professional but does not include the provision of dental services by a dentist; and
- (b) duly makes an application for registration before 1 October 2017 under Part 2 of the Act as a person who carries on or manages a private dental practice.

(2) This paragraph applies to any person who—

- (a) carries on or manages a private dental practice which consists of or includes the provision of dental services by a dentist; and
- (b) duly makes an application for registration before 1 April 2018 under Part 2 of the Act as a person who carries on or manages a private dental practice.

(3) Section 11(1), (5) and (6) of the Act will not apply to the persons referred to in paragraph (1) or (2) in respect of the private dental practice—

- (a) until such time as the application is granted, either unconditionally or subject only to conditions which have been agreed in writing between him or her and the registration authority; or
- (b) if the application is granted subject to conditions which have not been agreed, or is refused—
 - (i) if no appeal is brought, until the expiration of the period of 28 days after service on him or her of the registration authority's decision; or
 - (ii) if an appeal is brought, until it is determined, abandoned or withdrawn.

Revocations

41. Subject to regulation 42, the following Regulations are revoked—

- (a) the 2008 Regulations;
- (b) the 2011 Regulations.

Transitional savings

42.—(1) The 2008 Regulations continue to apply in relation to a dentist until the date on which the provider of the private dental practice in which the dentist works is registered under Part 2 of the Act.

(2) Subject to paragraph (3) where a dentist works in more than one private dental practice, the 2008 Regulations will continue to apply to that dentist until the provider of each of the private dental practices in which the dentist works is registered under Part 2 of the Act.

(3) The 2008 Regulations will no longer apply to the dentist in respect of the private dental practice in which he or she works once the provider of that private dental practice has registered under Part 2 of the Act.

(4) Where an application for registration, for cancellation or for the variation or removal of a condition is made by a dentist but is not determined before the coming into force of these Regulations, the application will be considered as if the 2008 Regulations were still in force, and the registered person must provide to the registration authority any other information or documents that the registration authority may require.

(5) For the purposes of this regulation, references to a dentist means a dentist registered to provide private dental services and who works in a private dental practice.

23rd February 2017

Vaughan Gething
Cabinet Secretary for Health, Well-being and
Sport, one of the Welsh Ministers