

Explanatory Memorandum to accompany the following subordinate legislation-

- 1. Care Standards Act 2000 (Extension of the Application of Part 2 to Private Dental Practices) (Wales) Regulations 2017,**
- 2. Private Dentistry (Wales) Regulations 2017; and**
- 3. Registration of Private Dentistry (Wales) Regulations 2017.**

This Explanatory Memorandum has been prepared by the Primary Care Division of the Directorate of Health Policy and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the above regulations.

I am satisfied that the benefits outweigh any costs.

Vaughan Gething
Cabinet Secretary for Health, Well-being and Sport

27 February 2017

1. Description

These Regulations operate together to form a new framework for the regulation of private dental practices in Wales. Persons who carry on or manage the provision of private dental services by a dentist or relevant professional services by a dental care professional are required to register with Healthcare Inspectorate Wales (who act on behalf of the Welsh Ministers) under Part 2 of the Care Standards Act 2000.

The Private Dentistry (Wales) Regulations 2017 revoke and replace the Private Dentistry (Wales) Regulations 2008 and the Private Dentistry (Wales) (Amendment) Regulations 2011.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

None.

3. Legislative background

Part 2 of the Care Standards Act 2000 (“the Act”) provides for the registration and inspection of establishments and agencies in Wales by the Welsh Ministers (the registration authority).

Section 42 of the Act provides the Welsh Ministers with the power to make regulations to extend the regulation and inspection regime under Part 2 of the Act to persons who provide dental services (that are similar to those which may be provided by the NHS), encompassing registration, regulation and enforcement, including both civil and criminal enforcement.

This power was exercised, together with section 22 of the Act, to make the Private Dentistry (Wales) Regulations 2008 (“the 2008 Regulations”) applicable to private dentists.

Dentists who provide private dental services solely in NHS hospitals or solely in independent hospitals are not regulated by the 2008 Regulations. Persons who carry on or manage independent hospitals must be registered with HIW and comply with the Independent Healthcare (Wales) Regulations 2011 (“the IHC Regulations”) and National Minimum Standards for independent hospitals.

Dentists who provide private dental services (but do not work solely in NHS hospitals) which include the provision of specialised dental treatment using Class 4 laser products must also register their service provision with Health Inspectorate Wales (“HIW”) as an independent hospital. Dentists who provide private treatment using lasers may work in mixed NHS/private practices although they provide private treatment using the laser.

Existing regulation applies only to private dentists in Wales. It does not extend to dental care professionals such as dental hygienists.

These Regulations replace the 2008 Regulations and are also made under powers in Part 2 of the Act. The Care Standards Act 2000 (Extension of the Application of Part 2 to Private Dental Practices) (Wales) Regulations 2017 are made using the power in section 42 to prescribe a person who carries on or who manages a private dental practice and provide that the regulation making powers in Part 2 of the Act apply in relation to such persons with modifications where relevant. The regulation making powers which are applied are listed in regulation 3(2) with the modifications set out in the Schedule. The Registration of Private Dentistry (Wales) Regulations 2017 and the Private Dentistry (Wales) Regulations 2017 were made under the extended and modified powers in Part 2 of the Act.

These Regulations will apply where the private dental practice consists of or includes the provision of private dental services by dentists or relevant professional services by dental care professionals (dental hygienists, dental therapists or clinical dental technicians).

However, they will not apply where the provision of private dental services are by dentists who work solely in NHS hospitals or independent hospitals. They will also not apply where the provision of relevant professional services are by dental care professionals working solely in independent hospitals.

These Regulations are subject to the negative resolution procedure.

4. Purpose & intended effect of the legislation

These Regulations when read together:

- Extend Part 2 of the Act to require persons who carry on or manage an undertaking which consists of or includes the provision of private dental services by dentists, to register with HIW in respect of the whole practice, rather than each dentist being required to register individually.
- Extend Part 2 of the Act to require the persons who carry on or manage an undertaking which consists of or includes the provision of relevant professional services by dental care professionals from their own premises, to register with HIW in respect of their practice. For example, registered dental care professionals who provide private hygienist services.
- Improve, quality and safety by aligning the standards for Private Dentistry with the Health and Care Standards (the standards of healthcare applied in NHS dental practices) and ensuring consistency as far as possible with the National Minimum Standards for Independent Health Care Services in Wales.
- Remove onerous burdens on dentists for example-
 - The requirement to have a separate registration with HIW as an independent hospital if dental treatment is provided using a Class 4 laser. However, separate registration as an independent hospital will still be required if a Class 4 laser is used to provide

- treatment for purposes not related to dentistry (for example, skin rejuvenation or hair removal).
- The requirements to have an enhanced Disclosure and Barring Service (“DBS”) check every 3 years. The new regulations will align the DBS requirements with those required by the NHS and include checks for dental care professionals.

There are approximately 450 dental practices in Wales. The majority of those practices provide both NHS and private services.

In *Together for Health, a National Oral Health Plan for Wales 2013 – 2018* the Welsh Government made the commitment to work with the dental profession and other stakeholders to revisit the Private Dentistry (Wales) Regulations 2008 and in particular, consider whether and how dental practices, rather than individual dentists, can register to provide private dental care. In addition the Welsh Government agreed to seek advice on how private dentists who provide special dental treatment using a Class 4 laser product (and are registered by HIW as an independent hospital) could comply with meeting the *National Minimum Standards for Independent Healthcare* so that standards for private dentistry are consistent with NHS services.

In 2013 the GDC made a decision to allow direct access. This permits certain dental care professionals, particularly dental hygienists, dental therapists and clinical dental technicians to provide appropriate dental care to patients/service users without having to see a dentist first. The existing regulatory framework only requires dentists to register with HIW, not dental care professionals. Therefore it is currently possible for private direct access dental care professionals to operate their own practice in Wales without registration with HIW and without the safeguards registration offers to patients and the practice.

Under the existing 2008 Regulations a dentist registered with HIW has to have an enhanced DBS every 3 years. This is in direct contrast with dentists who want to work in NHS dental practice in Wales - once they submit an enhanced criminal record certificate for inclusion in the health board NHS Dental Performers List, they do not require another check unless they move to another health board or commit an offence which requires another check.

Intended effect of the legislation

The Care Standards Act 2000 (Extension of the Application of Part 2 to Private Dental Practices) (Wales) Regulations 2017 extend the application of regulation making powers in Part 2 of the Care Standards Act 2000 (within necessary modifications) to persons who carry on or who manage a private dental practice. A private dental practice is defined in regulation 2 of these regulations and it captures both the provision of private dental services by dentists and relevant professional services by dental care professionals. Using these extended regulation making powers, the Welsh Ministers have made the Registration of Private Dentistry (Wales) Regulations 2017 (the

“Registration Regulations”) and the Private Dentistry (Wales) Regulations 2017 (“the 2017 Regulations”).

The Registration Regulations set out requirements relating to the registration process, including information and documents that applicants from persons who wish to carry on or manage a private dental practice must provide to HIW, and requirements in relation to applications to cancel registration and to vary or remove conditions.

The 2017 Regulations set out requirements that must be met by the registered person in respect of the private dental practice. They make provision about matters including:

- the fitness of the persons carrying on or managing the private dental practice;
- the conduct of the private dental practice including the quality of the services to be provided, suitability of the premises and staff, safeguarding of patients and financial viability of the practice;
- the giving of notices to the registration authority where certain events occur such as the death or serious injury of a patient, the absence of the manager, significant changes to the premises, where the registered person is convicted of any criminal offence, or where liquidators are appointed;
- required procedures for resuscitation of patients and use of Class 3B or 4 laser products;
- the sanction for failure to comply with breaches of requirements in the regulations;
- the necessary transitional, saving, revoking, amending and modifying provisions;
- the annual fee and the fee for applications to vary or remove a condition of registration.

The 2017 Regulations remove the requirement for a person to register as an independent hospital where a Class 4 laser is used by or under the supervision of a dentist or dental care professional in a private dental practice for dental treatment purposes.

Transitional provisions:

- *Dental care professionals*

Persons who were carrying on or managing a private dental practice **immediately before 1 April 2017**, which consist of or includes the provision of private direct access relevant professional services by a dental care professional must submit an application for registration to HIW by **1 October 2017**;

- *Dentists*

Persons who were carrying on or managing a private dental practice **immediately before 1 April 2017** which consist of or include the

provision of dental services must submit an application for registration to HIW by **1 April 2018**;

Revocations and savings:

The 2017 Regulations revoke the 2008 Regulations and the Private Dentistry (Wales) (Amendment) Regulations 2011. However, the following saving provisions are made in relation to dentists registered under the 2008 Regulations:

- The 2008 Regulations will 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.
- 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.
- The 2008 Regulations will no longer apply to the dentist once the provider of all private dental practices where the dentist works has registered under Part 2 of the Act.
- 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 by HIW 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.

Fees:

Schedule 5 to the 2017 Regulations prescribes the following -

- No fee is payable in respect of an application to register under Part 2 of the Act.
- The annual fee payable by the registered provider of a private dental practice is £500. However, where the private dental practice consists of one dentist only and that dentist provides private dental services and dental services for the purposes of the National Health Service (Wales) Act 2006, the fee payable is £300.
- The fee for an application to vary a condition of registration is-
 - £500 for a major variation
 - £250 for a minor variation
- The fee for an application to remove a condition of registration is £50.

5. Consultation

Please see part 2.

PART 2 – REGULATORY IMPACT ASSESSMENT

We have identified two options:

- **Option 1: Not to introduce new regulations to regulate private dental practices**
- **Option 2: Introduce new regulations to regulate private dental practices**

6. Options

Option 1:

Not to regulate private dental practices

Under this option the current approach will remain. This will mean that the requirement to register with HIW will continue to apply only to individual dentists. Private direct access dental care professionals will be allowed to continue to operate their own practices in Wales without registration with HIW and without the safeguards registration offers to patients and the practice. Improvements relating to quality and safety will not be imposed prolonging the lack of synergy between the NMS for Independent Health Care Services in Wales and the Health and Care Standards for Wales. Inconsistencies relating to Disclosure and Barring Service checks between private dentists and dentists working in the NHS will continue. Unnecessary burdens will remain such as the need for private dentists providing treatment using a Class 4 laser to register both as a dentist with the GDC and as an independent hospital.

Option 2:

Introduce new regulations

Under this option all Private Dental Practices and Private Direct Access practices will be regulated by HIW. This will extend HIW's regulatory remit and act as a strong mechanism to encourage continuous improvement in the provision of private dental services. It will also provide for greater consistency between private and NHS practices in terms of meeting standards.

7. Costs and benefits

Costs

The costs of regulation include costs associated with HIW's registration process, the inspection of dental practices providing private dental services,, the preparation of inspection reports, the handling of any complaints and dealing with on-going registration related issues.

No fee is currently payable for registration, or to vary or move a condition of registration.

The existing annual fee (£75 per annum) does not reflect the cost of registration and the recently introduced quality assurance systems and practice inspection/peer review process. The level of any new fee is less than that paid by practices in England – currently between £600 and £1300 per annum depending on the size of the practice.

The new regulations prescribe a higher rate fee of £500. This is the same sum paid by private general medical practices who register and less than the sum required for dental practices registering in England. Single dentist practices which provide both NHS and private services will pay an annual fee of £300.

It is anticipated that any unforeseen costs to HIW can be borne from existing and future budgets and through increases in annual registration fees. It is anticipated any proposed increase in fees will not adversely impact competition between dental practitioners, since they will apply uniformly to all dental practices.

The increased practice registration fee will be offset by reduced costs of not having to have 3 yearly Disclosure and Barring Service checks. For larger practices the reduction in individual registration will also offset the increased fee for practice registration. Single handed practices or those with only 2 or 3 dentists will have to pay more than under the current system. However the process of practice registration, inspection and reporting involves almost the same level of input as that required for a large practice.

The 2017 Regulations will not act as a restriction on new market entrants and do not favour any particular type of private dental practice or individual dental practitioner.

Benefits

Regulating private dental practices will act as a strong mechanism to encourage continuous improvement in the provision of private dentistry and private direct access dental services. It will also provide assurance to the public in terms of the quality and safety of services provided at those practices – ensuring that staff are suitably competent, trained and indemnified to provide services.

No impact on the general public, local government or the third sector is foreseen.

Summary and preferred option

Option 2 is the preferred option because it fits the Welsh Government's policy intention that persons who carry on or manage a private dental practice or

provide private direct access dental services in Wales must be registered with HIW.

8. Consultation

Section 22(9) of the Act requires the Welsh Ministers to consult on regulations made under section 22 which effect any substantial change in the provision made by those regulations.

A three month public consultation exercise was therefore undertaken between 29 January and 22 April 2016. While the response to the consultation exercise was broadly in support of the policy intention of Welsh Government, a number of detailed responses have helped Welsh Government to enhance and clarify the regulations. Welsh Government have produce a report in response to the consultation which can be found here:

<https://consultations.gov.wales/consultations/draft-private-dentistry-wales-regulations-2016>