

Explanatory Memorandum to the Private Dentistry (Wales) (Amendment) Regulations 2011

The Explanatory Memorandum has been prepared by the Department of Health and Social Services and is laid before the National Assembly for Wales 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 Private Dentistry (Wales) (Amendment) Regulations 2011. I am satisfied that the benefits outweigh any costs.

Lesley Griffiths AM

Minister for Health and Social Services, one of the Welsh Ministers

6 November 2011

Description

1. The Private Dentistry (Wales) Regulations 2008 require a dentist who provides any dental services in Wales, otherwise than for the purposes of the National Health Service (Wales) Act 2006, to register with Welsh Ministers through Healthcare Inspectorate Wales (HIW). These regulations amend the Private Dentistry (Wales) Regulations 2008. Schedule 1 to these Regulations prescribes the manner in which provisions of Part II of the Care Standards Act 2000 apply to persons providing private dental services.

Matters of Special Interest to the Constitutional and Legislative Affairs Committee

2. None

Legislative background

3. The Welsh Ministers have the power to make regulations under section 42 of the Care Standards Act 2000 (the Act) to provide for Part II of the Act to apply, with modifications, to prescribed persons. This power was exercised to apply Part II of the Act to private dentists by the Private Dentistry (Wales) Regulations 2008 ("the Regulations"). It includes power to make further modifications in the application of the Act. The Welsh Ministers have power to make and to amend regulations as to fees and the provision of services and information under sections 12, 16 and 22 of the Act. Section 25(1) provides a

power to specify that contravention of certain regulations shall be an offence and section 33 provides a power to require persons registered under the Act to submit annual returns. The Regulations came into force on 1 January 2009. The Regulations can be viewed by accessing the following link

http://www.opsi.gov.uk/legislation/wales/wsi2008/wsi_20081976_en_1

Purpose and intended effect of the regulations

4. The private dentistry regulations came into force on 1 January 2009 and since that time HIW has registered over 1200 private dental practitioners who provide private dentistry.

5. The purpose of the Regulations is:

(a) To address unintended gaps and consequences of Regulations :

- To allow a registered dental practitioner (who has “reasonable cause to believe that a patientis not receiving proper care”) to undertake, with the consent of the patient, an examination (Section 31(5) of the 2000 Act.
- Exempting from regulation private dentistry carried out in an NHS Hospital or in a hospital regulated under the Care Standards Act 2000.
- A provision to require private dental practitioners to complete a self-assessment about the ongoing quality of their dental treatment and services (an Annual Return¹).
- Extending the range of regulatory offences
- A temporary exemption from registration for newly qualified dentists, providing private dental treatment, who are undertaking vocational training.

(b) To clarify that the additional enforcement powers for Welsh Ministers (inserted as amendments to the Care Standards Act 2000 by Schedule 5 of the Health and Social Care Act 2008) do apply to the Regulations..

(c) To amend the registration fee, the annual fee and fees for variation of conditions of registration.

Regulatory Impact Assessment

Options

6. Option 1: Do not introduce the amendments. This will result in HIW’s regulatory powers not being as strong as possible, and HIW’s costs of regulation not being substantially recovered.

7. Option 2: Introduce the amendments. Introducing the amendments will address the unintended gaps and consequences of the Regulations, ensure that costs of regulation continue to be substantially recovered and strengthen HIW’s regulatory powers.

¹ See Section 33(1) Care Standards Act 2000

8. It is considered that option 2 is the better option.

Risks of not proceeding

9. Failure to proceed will mean that the unintended gaps and consequences of the Regulations will remain unaddressed, the costs of HIW regulation will not be substantially recovered, and HIW's regulatory powers will not be fully strengthened.

Competition Assessment

10. It is anticipated that the proposed increase in fees (from £50 to £75) will not adversely impact competition between providers, since they will apply uniformly to all dental practitioners.

11. The proposed amendments will not act as a restriction on new market entrants and do not favour any particular dental practitioner.

Summary

12. In summary, the proposed amendments will strengthen HIW's regulatory powers, and will enable HIW to continue to ensure that the cost of regulation is substantially recovered.

Equality Impact Assessment

13. An Equality Impact Assessment has been undertaken – **Annex 4** refers.

Consultation

14. The proposed amendments to the Regulations were subject to an eight week public consultation which closed on 16 November 2010. The organisations / individuals who were consulted on the proposals are detailed at **Annex 1**.

15. In total, 25 organisations / individuals responded - **Annex 2** refers. A summary of the responses is detailed in the following table:

Question	Number of respondents	Agreed	Disagreed	No view
1. Do you agree with the proposal to require private dental practitioners, to complete a self-assessment about the ongoing quality of their dental treatment and services	24	19	5	0
2. Do you agree with the	22	19	1	2

proposal to extend the list of professionals to dentists who may examine a consenting patient				
3. Do you agree with the proposal to exempt some practitioners from regulation	24	12	8	4
4. Do you agree with the proposal to make regulation 6, 7, and 18 an offence	23	10	7	6
5. Do you agree with the new regulations and/ or sub sections that are proposed	22	14	5	3
6. Do you agree with the proposal to increase regulatory fees	25	6	18	1
7. Are there any proposals that are not relevant for private dentists	16	1	9	6

16. Overall, the response to the proposed amendments was mixed. In particular, respondents expressed concern about the proposal to extend the range of regulatory offences and the proposal to increase regulatory fees. Respondents also highlighted the need for guidance to be issued by HIW to ensure clarity of interpretation of the proposed changes and for easier administration of the fee payment. Respondents also highlighted their continuing discontent with the policy of registering individual dental practitioners as opposed to dental practices. Given that the policy to register practitioners was made 3 years ago, it is proposed that an assessment of practitioner registration will be undertaken. Any proposed changes will, of course, be subject to public consultation.

17. No changes to the draft legislative amendments are proposed as a result the issues raised by respondents. The detailed response to the consultation questionnaire is set out at **Annex 3**.

List of organisations / persons consulted

Private Dental Practitioners registered with Healthcare Inspectorate Wales
Chief Executives, Local Health Boards
Directors of Primary Care, Community and Mental Health, Local Health Boards
Chief Officer, Board of Community Health Councils
Secretaries, Welsh Local Dental Committees
British Dental Association (Wales)
Chief Executive, Public Health Wales
Team Lead, Dental Public Health, Public Health Wales
Welsh Dental Committee
Welsh General Dentists Practitioners Committee
Dental Services, NHS Business Services Authority
Community Dental Directors, Wales
General Dental Council
Denplan

List of organisations / persons who responded to the consultation

British Dental Association (Wales)
Ceders Dental Practice
Cwm Taf Local Health Board
Graham Roy Dental Care (2 separate responses)
Dental Division, Cardiff and Vale University Health Board
Beaumaris Dental Health Care
Board of Community Health Councils in Wales
Welsh Dental Committee
Aneurin Bevan Health Board
Alan Barclay Dental Surgery
Public Health Wales
Leslie Hooper
Colin McCubbin Dental Practice
Deintyddfa Llys Einion Dental Practice
Tara Martin Dental Care
Russell Street Dental Clinic
Willie Jack Dentistry
St. James Street Dental Practice, Monmouth
Sion Meredith Griffiths Dental Clinic
The Willows Dental and Implant Practice
Gwersyllt Dental Practice
Cemaes Bay Dental Practice
Agincourt Dental Surgery
Smiles Better, Abergavenny

Analysis of the Response to the Questionnaire

The following is a summary of the responses to each of the consultation questions together with the Welsh Government's response

1. Do you agree with the proposal to require private dental practitioners, to complete a self- assessment about the ongoing quality of their dental treatment and services

24 organisations/ individuals responded. 19 respondents agreed with the proposal. 5 respondents did not agree with the proposal. Respondents highlighted the following:

- Clarity of the meaning of “ongoing quality of their dental treatment and services”.
- Clarity as to whether the annual audit document is the QAS.
- Clarification as to whether mixed practice practitioners need to complete this additional document.
- Clarity about the scope of the services provided in the annual report .
- Concern about the validity of self assessment and the need for subsequent validation against standards.
- Concern about duplication of effort.
- Concern about why QAS should apply to private practice since the justification of QAS is based on NHS contractual commitment
- Need to consider the future requirements of revalidation.
- The need for the self assessment to mirror the NHS requirement.

Welsh Government response

The proposed amendment 2 (6) relates to assessing and monitoring the quality of service provision including annual reports. This amendment requires registered dental practitioners to send to the registration authority (HIW) a written annual assessment / report setting out the scope of the services provided. Providing an annual assessment / report is not an annual requirement, but will be a requirement on request from HIW.

Where a request for an annual assessment / report is made by HIW, it is proposed that format of the annual assessment / report will be similar to the Public Health Wales QAS assessment which is currently completed by those dental practitioners on the NHS Performers List.

In order to reduce duplication of effort, for those dental practitioners who have already completed the QAS assessment as an NHS Performers List requirement, it is proposed that these dental practitioners forward a PDF copy of the Quality Assurance document to HIW. Wholly private dental practitioners will also be asked to complete the QAS assessment which will be amended to relate to wholly private dental practitioners. This will enable consistent comparative analysis to be undertaken across all registered persons. In relation to the concerns identified about the validity of the self assessment, proposed amendment 2 (6) (3) requires registered persons to

take all reasonable steps to ensure that annual assessment / report is not misleading or inaccurate.

2. Do you agree with the proposal to extend the list of professionals who may examine a consenting patient (where that professional has “reasonable cause to believe that a patientis not receiving proper care”) to include a dentist in addition to the current list of doctor and nurse

22 organisations/individuals responded. 19 respondents agreed with the proposal. 1 respondent did not agree with the proposal. 2 respondents did not express a view. Respondents highlighted the following:

- Clarity that only a dentist (and not a nurse or doctor), will not undertake an examination of a consenting patient.
- The need for HIW to issue guidance outlining the circumstances when an examination of a patient may be required.
- Clarity that this proposed amendment complies with the Dentists Act.

Welsh Government response

The purpose of this amendment is to ensure that where it is considered necessary for an examination of a consenting patient to be undertaken that this examination can be undertaken by a dentist. Under the law as it stands such examinations can only be undertaken by a medical practitioner or a registered nurse. In most, if not all cases of dental treatment, it will be more appropriate for the examination to be carried out by a dentist who is qualified to do so by virtue of the Dentists Act 1984. HIW will issue guidance outlining the circumstances when an examination of a patient may be required.

3. Do you agree with the proposal to exempt from regulation:

a) **private dentistry carried out in an NHS Hospital where the dentist is directly employed by an NHS body in Wales and only provides private dental services in that NHS hospital and**

b) **private dentistry carried out in and for the purposes of an independent hospital regulated under the Act, and Independent Health Care (Wales) Regulations 2011 (most commonly a hospital by reason of the fact that it provides dental treatment under general anaesthesia) and vocational training?**

24 organisations/individuals responded. 12 respondents agreed with the proposal. 8 respondents did not agree with the proposal. 4 respondents did not express a view. Respondents highlighted the following:

- The amendment to exempt private dentistry carried out in an NHS hospital (where the dentist is directly employed by an NHS body in Wales and only provides private dental services in that NHS hospital) and private dentistry carried out in and for the purposes of an independent hospital regulated under the Act through the Independent Health Care (Wales) Regulations 2011 (most commonly a hospital by reason of the fact that it provides dental treatment under general anaesthesia), is not supported since this is against the principles of the

Private Dentistry regulations which require practitioners to register with HIW rather than practices to register with HIW.

- It is unfair for NHS hospitals and independent hospitals to be exempt.
- Dentists should not be providing private services under a Vocational Training contract which is NHS funded and a supervised activity. Private work provided by a trainee is not part of the contract.
- This exemption should be widened to dentists new to Wales and short term locums.
- This proposal supports the pragmatic position of registering premises rather than an individual.
- Clarification as to whether staff grades and associate specialists who are not on the GDC specialist list are barred from undertaking private work in hospitals and if so can they assist specialists/ consultants.

Welsh Government response

A primary aim of the Regulations is for dental practitioners who provide private dental treatment to patients in a community practice setting to register with HIW.

Dental practitioners on a specialist register and who provide a service in an NHS hospital, operate largely within the clinical governance arrangements of the NHS hospital that they are employed by and have to provide services which comply with the *Doing Well, Doing Better Standards for Health Services in Wales*. NHS hospitals are subject to inspection by HIW under the Health and Social Care Act 2003. Given that these dental practitioners operate solely within a secondary care health establishment and are already subject to HIW inspection, it is considered that requiring a dentist who is on a specialist register and who is employed to provide services in connection with that specialism in a health service hospital to register with HIW under the Private Dentistry (Wales) Regulations 2008, is an unnecessary bureaucracy.

Independent hospitals are registered under the Care Standards Act 2000. Dental practices which provide private dental treatment under general anaesthesia are a class of independent hospital under the Act. Those who carry on independent hospitals are required to register with HIW. The consequence of regulation of a hospital (including dental hospitals providing treatment under general anaesthetic) means that the establishment is regulated against the Independent Healthcare (Wales) Regulations 2011. It is therefore considered an unnecessary bureaucracy to require a dentist who provides private dental services only in and for the purposes of an independent hospital to register as a private dentist. The provision of dental services in such circumstances will be regulated as part of the registered independent hospital's activities.

The proposed amendment 2 (b) (c) exempts dentists working under a vocational training contract who have made an application to register with HIW (but the application has not yet been determined by HIW) and who during that period undertake work on private patients (note that the private

work is not undertaken under the NHS contract) as well as NHS funded patients.

Exemptions for dentists new to Wales, including locums, have been considered. For example, a three month exemption on registration for dentists wishing to practice in Wales but who were on the Performers List in England was considered. However, it was considered that this proposal could breach Article 18 of the Treaty on the functioning of the European Union on the grounds of indirect discrimination given the proportions of UK and non-UK EU nationals who could show that they are actually on UK performers lists.

Staff grades and associate specialists who are not on the GDC specialist list are not barred from undertaking private work in hospitals.

Given that the policy to register practitioners was made 3 years ago, it is proposed that an assessment of practitioner registration will be undertaken. Any proposed changes will, of course, be subject to public consultation.

4. Do you agree with the proposal to make regulations 6, 7, and 18 an offence?

23 organisations/individuals responded. 10 respondents agreed with the proposal. 7 respondents did not agree with the proposal. 6 respondents did not express a view. Respondents highlighted the following:

- Regulation 7 (notice of changes of name and address before application determined) is discriminatory as it applies mainly to females.
- Regulation 18 (notice of changes of changes following registration) is disproportionate and could lead to referral to the GDC with consequences for NHS practice.
- This is an additional bureaucracy.
- The dental regulatory framework already has sufficient safeguards.
- Making these minor areas of non-compliance regulatory offences is excessive.
- The current regulatory sanction should be sufficient and making a breach of these regulations an offence will not benefit patient safety.

Welsh Government response

Making it an offence to breach the regulations is necessary to ensure that HIW receives the information it needs to regulate effectively.

Regulation 7 is not directly discriminatory. It applies to all registered persons where a change to a name or address is made after the application has been made and before it has been determined. Even if it is the case that proportionately more women change their names than men, it is a legitimate legislative aim for all registered persons to inform the registration authority of their current names and addresses. It is essential for the registration authority to be aware of current names and addresses to ensure effective regulation

and to avoid any confusion in the identity of registered persons and applicants.

These proposed offences are consistent with the regulatory offences in relation to the registration of dental practitioners in England under the Care Quality Commission (Registration) Regulations 2009 and the regulatory offences set out in the Independent Health Care (Wales) Regulations 2011 which covers persons carrying on or managing independent hospitals, independent clinics and independent medical agencies who are also registered with HIW under the Act.

HIW will take a proportionate view in dealing with any breach of regulation and any action taken by HIW will be in accordance with their enforcement procedures.

5. Overall, do you agree with the new regulations and/ or sub sections that are proposed?

22 organisations/individuals responded. 14 respondents agreed with the proposal. 5 respondents did not agree with the proposal. 3 respondents did not express a view. Respondents highlighted the following:

- The regulations may be open to interpretation and risk being extended beyond what is required unless there is background explanation
- HIW regulation is duplication since mixed funded practices follow LHB regulation.

Welsh Government response

HIW will ensure that the amendments to the regulations will be supported by explanatory guidance to ensure clear and consistent interpretation.

The inspection of private dental treatment against the same standards of healthcare applied in NHS practices is integral to the on-going development of consistent safe and high quality care for all patients in Wales.

6. Do you agree with the proposal to increase regulatory fees?

25 organisations/individuals responded. 6 respondents agreed with the proposal. 18 respondents did not agree with the proposal. 1 respondent did not express a view. Respondents highlighted the following:

- Any increase in fees needs to be fully justified and transparent
- Initial poor management of projected costs
- Become more efficient
- Practitioners are penalised for working within Wales

Welsh Government response

It is considered that the proposed increase in regulatory fees is not unreasonable and that dental practitioners are not financially penalised for

working in Wales. Respondents may wish to note that the regulatory regime in England requires dental practices (both NHS and private) to register with the Care Quality Commission. Where the practice operates from only 1 location the registration fee is £800.

http://www.cqc.org.uk/publications.cfm?fde_id=18096

7. Are there any proposed new regulations that are not relevant for private dentists?

16 organisations/individuals responded. 1 respondent expressed a view that the proposed new regulations were not relevant for private dentists. 9 respondents expressed a view that the proposals were relevant for private dentists. 6 respondents did not express a view.

No key issues were highlighted in relation to this question.

8. Other issues which have been highlighted

A restriction should be placed on dentists to provide private care until their application for registration has been processed

Welsh Government response

The Regulations require that a dentist who wishes to provide private dentistry must register with the appropriate authority (Healthcare Inspectorate Wales on behalf of Welsh Ministers) under the Act. Subject to the proposed exemption for dentists who are under a vocational training contract, a person who provides private dentistry without being registered commits an offence under the Act. When the Regulations came into force provision was made for dentists to continue to provide services privately pending consideration of the applications made within 6 months of commencement. All of those applications have now been determined.

Dentists would like to receive an acknowledgment of their registration and to be able to pay through a recurring instruction to their bank and for the system to be implemented more effectively

Welsh Government response

HIW will send out a receipt of payment as a matter of routine. HIW will also consider allowing payments through a recurring instruction.

The requirement to return certificates after retirement / death/ emigration is excessive.

Welsh Government response

If a person registered with HIW retires, or dies or emigrates to another country their registration with HIW will be cancelled. The need for the registration certificate to be returned to HIW is an important regulatory control.

Is there a need for this additional legislation?

Welsh Government response

Yes. Many of these amendments seek to reduce unnecessary duplication of regulation.

There is a need to ensure that National Minimum Standards for Private Dentistry are reviewed and aligned with, where possible, the new Healthcare Standards for *Wales Doing Well Doing Better*

Welsh Government response

The National Minimum Standards for Private Dentistry are currently being reviewed. Subject to Ministerial approval, the intention is to consult on the revised standards later this year.

There is a need for Wales to avoid the following concerns about regulation of dentists by the Care Quality Commission in England:

- **The imposition of unnecessary duplication of process and paperwork – for example, the information gained through an enhanced CRB check in relation to convictions and cautions is also reported to the GDC.**
- **The need for regulation and its processes to demonstrate actual improvements in patient care**
- **The need to ensure that governance processes are appropriate and proportionate**
- **The need to reduce the bureaucratic burden**

Welsh Government response

The regulation of private dentistry in Wales enables the inspection of private dental treatment against the same standards of healthcare applied in NHS practices which is integral to the on-going development of safe, high quality care for all patients in Wales. The level of regulation in Wales is appropriate and proportionate to risk. The current proposed amendment to the regulations includes the exemption of certain categories of dentists who are already regulated by HIW under the Health and Social Care Act 2003 or under the Act or are under supervision through vocational training. The need for dentist to undergo enhanced CRB checks mirrors the necessity for other healthcare professionals and clinicians to undergo enhanced CRB checks if they are working with children or vulnerable adults.

Regulation of private dentistry should be undertaken by health authorities (Local Health Boards)

Welsh Assembly Government response

Local Health Boards do not have the powers to regulate private dentistry. Although LHBs could be given such powers by the Assembly, this is not under consideration given the complexity of LHBs principal role of ensuring effective planning and delivery of the local NHS system. Regulation through HIW will provide independent assurance for patients and the public that services are safe and are good quality.

The level of regulation is disproportionate to running a safe environment for patients

Welsh Government response

It is considered that the level of regulation in Wales is appropriate and proportionate to risk. The current proposed amendment to the regulations includes the exemption of certain categories of dentists who are already inspected by HIW under the Health and Social Care Act 2003 or regulated under the Act.

Equality Impact Screening Assessment:

Proposed Amendments to the Private Dentistry (Wales) Regulations 2008

The Private Dentistry (Wales) Regulations 2008 (“the Regulations”) require a dentist who provides any dental services in Wales, otherwise than for the purposes of the National Health Service (Wales) Act 2006, to register with Welsh Ministers through Healthcare Inspectorate Wales (HIW).

A number of proposed amendments to the Regulations have been proposed. The amendments seek to remove dental practitioners from regulation who provide care in establishments regulated by HIW under the Care Standards Act 2000 or the Health and Social Care Act 2003. The proposed amendments also strengthen existing regulation by requiring dental practitioners to complete self assessments about the quality of treatment and by extending the range of regulatory offences. The amendments also propose an increase in the regulatory fees imposed on dental practitioners. The proposals were subject to an eight week public consultation which closed on 16 November 2010.

<http://wales.gov.uk/consultations/healthsocialcare/dentistryregulations/?lang=en&status=closed>

Equality Strand	Summary of evidence Identified and gathered	Weighting [<i>Credibility of evidence</i>] Tick appropriate box			Relevance of evidence [<i>Equality issues raised by evidence</i>]	Policy or practice relevance to equality strand Tick appropriate box			
		Unsatisfactory	Satisfactory	Strong		No relevance	Low	Medium	High

Disability	There is no evidence to suggest that this proposal favours a person with a disability.			√	None	√			
Race	There is no evidence to suggest that this proposal favours a person of a specific race.			√	None	√			
Gender and Gender Reassignment	There is no evidence to suggest that this proposal favours a person of a specific gender or a person who has undergone gender reassignment.			√	None	√			
Age	There is no evidence to suggest that this proposal favours a person of a specific age.			√	None	√			
Religion and Belief and Non-Belief	There is no evidence to suggest that this proposal favours one particular religious group over another.			√	None	√			
Sexual Orientation	There is no evidence to suggest that that this proposal favours a person of a particular orientation			√	None	√			
Human Rights	This proposal is consistent with human rights legislation.			√	None	√			