

## **Explanatory Memorandum to the Private Dentistry (Wales) Regulations 2008**

This 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 24.1.

### **Description**

1. These Regulations require dental practitioners, who provide private dental services in Wales, to register with Welsh Ministers, through Healthcare Inspectorate Wales under Part II of the Care Standards Act 2000.

### **Matters of Interest to the Subordinate Legislation Committee**

2. These Regulations take forward a motion under former Standing Order 31 that was debated in plenary on 14 November 2006. A feasibility Study was considered by the former Health and Social Services Committee on 1 March 2007 and debated in plenary on 14 March 2007.

### **Legislative background**

3. 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 to prescribed persons, including persons providing dental services privately. The use of section 42 of the Act and the application of the whole of Part II of the Act to apply to persons who provide private dental services (that are akin to those which may be provided by the NHS) encompasses registration, regulation and enforcement, including both civil and criminal enforcement. The Regulations follow the negative procedure.

### **Purpose and intended effect of the legislation**

4. There are approximately 1530 dentists registered with the General Dental Council with addresses in Wales. Although exact numbers are not available, a high number of these dentists offer both NHS funded care and private dental services. NHS funded dental care / practices are currently subject to inspection, through the Dental Reference Services, but these inspections do not extend to the inspection of private dental services / treatment offered by NHS funded practices. In relation to those dental practices that are wholly privately funded, although no information is currently collected, it is estimated that of the 1530 dentists registered with the General Dental Council with addresses in Wales, that there are approximately 20 wholly privately funded dental practices in Wales involving approximately 50 dental practitioners. These wholly privately funded dental services are, currently, not subject to inspection.

5. These Regulations will require dental practitioners who provide private dental services in Wales to register with Welsh Ministers, through Healthcare Inspectorate Wales, under the Care Standards Act 2000. These dental practitioners will be required to meet the National Minimum Standards for Private Dental Services which mirror the standards of healthcare applied in NHS dental practices. The inspection of private dental treatment against the same standards of healthcare applied in NHS practices is integral to the on-going development of safe, high

quality care for all patients in Wales. The Regulations will also act as a strong mechanism to encourage continuous improvement in the provision of private dental treatment and the improvement of clinical governance throughout primary dental care in Wales.

## **Implementation**

6. If the Regulations are annulled it will mean that there will be no inspection of the provision of private dental treatment in Wales. This will impact adversely the improvement of healthcare and clinical governance in primary dental care.

## **Consultation**

7. Details of the consultation undertaken are provided as part of the Regulatory Impact Assessment below.

## **Regulatory Impact Assessment**

### **(i) Options**

#### 8. (a) To regulate private dental services

The Regulations require dental practitioners who provide private dental services in Wales to register with Welsh Ministers, through HIW

Advantages - These dental practitioners will be required to meet the National Minimum Standards for Private Dental Services which mirror the standards of healthcare applied in NHS practices. The inspection of private dental treatment against the same standards of healthcare applied in NHS practices is integral to the on-going development of safe, high quality care for all patients in Wales.

Disadvantages – Failure to regulate dental practitioners who provide private dental services in Wales will impact adversely the improvement of healthcare and clinical governance in primary dental care.

#### 9. (ii) To delay regulation until arrangements in England become clearer

The Health and Social Care Bill which is currently making its way through Parliament, sets out proposals for the establishment of the Care Quality Commission in England. The intention is for the Care Quality Commission to register / regulate NHS funded and privately funded healthcare providers in England. The Department of Health published a consultation paper in March 2008 - *The future regulation of health and adult social care in England: A consultation on the framework for the registration of health and adult social care providers* provides further details. The proposals include the registration of NHS funded and privately funded dental practices.

Advantages - the approach to regulate private dental treatment in Wales may be further developed taking into account the proposals being developed in England. This would assist in ensure a consistency of approach if Wales decided to mirror some aspects of the registration / regulation proposals in England.

Disadvantages – The Care Quality Commission (CQC) will reflect the merging of the Healthcare Commission, the Mental Health Act Commission's activities in England, and the Commission for Social Care Inspection in England. Subject to parliamentary approval, it is anticipated that the Care Quality Commission will be established April 2009. It is likely that the CQC will be prioritising the registration and regulation of NHS secondary care providers in 2009/10 and that arrangements for the registration and regulation of the NHS funded and privately funded primary care sector, including dental practices, may not be addressed until 2010 /11 at the earliest. Consequently, it is considered that the potential timescales for England to address regulation of private dental care are too distant to be a practical option to consider.

10. (iii) Not to regulate private dental treatment

Advantages - The resources devoted by HIW (in registering, regulating and enforcing the Care Standards Act) and the resources devoted by DRS (in inspecting private dental treatment) can be redeployed.

Disadvantages – The public in Wales will gain no assurance on the quality of private dental treatment.

Given the potential for private dental treatment to increase and the inherent risks to the public, it is considered that the advantages of inspection and regulation outweigh the disadvantages.

**(ii) Benefits**

11. Regulating private dental treatment will also act as a strong mechanism to encourage continuous improvement in the provision of private dental treatment and the improvement of clinical governance throughout primary dental care in Wales

**(iii) Costs**

12. HIW will regulate dental practitioners who provide private dental services in Wales. The costs of regulation include costs associated with the registration process, the inspection of private dental treatment, the preparation of inspection reports, the handling of any complaints and dealing with on-going registration related issues. The on-going costs are anticipated to be in the region of £60,000 to £90,000. These costs will be offset by registration and annual fees (based on £50 per registration / annual fee) that are expected to generate approximately £60,000 per annum. It is anticipated that any unfounded costs can be borne from HIW's existing and future budgets and through increases in annual registration fees.

**(iv) Competition Assessment**

13. The Regulations impact only dental practitioners who provide private dental services in Wales.

**(iv) Consultation**

14. On 1 October 2007, the Welsh Assembly Government launched a twelve-week public consultation on the draft Private Dentistry (Wales) Regulations and the

supporting draft National Minimum Standards for Private Dental Services. The draft Regulations required dental practitioners and clinical dental technicians, who provide private dental services in Wales, to register with Welsh Ministers, through HIW, under Part II of the Care Standards Act 2000. The list of bodies and individuals consulted is at Appendix 1.

16. Responses were received from 29 bodies and individuals - Appendix 2 refers. Overall, support for increased regulation was mixed. Many respondents did not fully understand the role of HIW and thought that the GDC provided sufficient regulation. Many respondents highlighted the need for clarity on the following areas:

- The need for clarity on how the draft regulations will be put into effect.
- The need for clarity about whether registration with HIW can be achieved within the prescribed timescales, given the need to have an enhanced CRB and the proposed six months transition period
- The need for clarity on why fees are proposed and what activities the fees will cover
- The need for clarity on complaints handling
- The need for clarity on offences and appeals mechanisms
- The need for clarity on the meaning of some specific words, such as “ as promptly as possible “
- The need to increase the transition period
- The need for certain regulations to be categorised as an offence

17. Respondents also required clarity on the following specific issues. Officials' response is also highlighted.

**Is there a need for hospital-based practitioners who provide private dental services to be regulated?**

Response: Yes. All practitioners who provide private dentistry to one or more patients at any one time are required to be registered.

**Can dental practitioners who provide specialist private dental treatment at a private clinic / independent hospital on an occasional basis, but whose main (NHS funded) employment is elsewhere, be exempt from registration?**

Response: No. We considered an exemption for dentists already registered under the Private and Voluntary Health Care (Wales) Regulations 2002 who provide dental treatment under general anaesthesia. However, as the current National Minimum Standards do not cover all dentistry treatment that is included in the new private dental regulations, it is not possible to provide an exemption.

**Will the Certificate of Registration clearly state that registration is with Welsh Ministers (with delegated decision making authority to the HIW) and not the GDC?**

Response: The certificate of registration will clearly state that the registration is with the WAG and this is provided for by virtue of regulation 8.

**Is there a need to clarify whether the address is the dental practitioner's home address or business address?**

Response: Yes. The applicant will be required on their application form to provide their home address and a contact address. Regulation 8, contents of certificates, will be amended to reflect this. Regulation 18 will have an additional sub-section to

require the dental practitioner to notify the HIW of any changes in their contact and home address.

**Is there a need to specify the English exam and the grade /score for both EEA members and non-EEA members?**

Response: No, we are unable to specify this. The GDC have set out the criteria below for non-EEA applicants to the dental register. Because EEA applicants are exempt from the English language requirement, WAG cannot go against that provision as it is set out in European Law.

Pre-examination language test

Dentists applying to sit the exam must demonstrate they have a good standard of English. Candidates are required to submit a single, Academic IELTS Test Report Form before their application will be accepted.

The form must:

- be no more than two years' old on receipt at the GDC
- show a minimum overall band score of 7.0
- show no score lower than 6.5 in any section

In sections where scores are given in whole numbers only, a minimum score of 7 is required. Dentists who are nationals of the EEA or entitled to be treated no less favourably than nationals of the EEA are exempt from the English language requirement. This is in accordance with European Law.

**In relation to Regulation 5 (2) is there a need to include an additional sub section (m) as follows “ details of any condition imposed on his or her registration by the General Dental Council or his or her inclusion on a Performers List”?**

Response: Yes. This suggestion will be incorporated into the regulations.

**Is there a need to amend the Regulations to accommodate the short notice of locum practitioners?**

Response No. Locums and locum agencies should be aware that the Regulations are in place through the General Dental Council.

**Is Regulation 12 sufficiently flexible to cater for the death, serious illness or other immediate event that may affect a practitioner?**

Response: Yes. The regulation as drafted caters for these circumstances

**In relation to Regulation 14 (1) (b) is there a need to clarify the interpretation of the words “as promptly as possible “ given that not all dental procedures are urgent?**

Response: Yes. It is considered that this sub-section of the regulation is no longer necessary as regulation 14 already requires treatment to be provided which meets the patients' needs, which would include timely treatment. This regulation will be removed from the final regulations.

**In relation to Regulation 14 (1) (c), it has been suggested that the legality of this section be confirmed.**

Response: This sub-regulation is consistent with regulation 14 of the Private and Voluntary Health Care (Wales) Regulations 2002.

**In relation to Regulation 14 (1) (c) it has been suggested that a caveat in inserted “ where evidence based guidelines have been agreed”**

Response: It would be problematic to amend the Regulation in line with this suggestion since there would be the need to interpret what was meant by 'agreed'.

**In relation to Regulation 14 is there a need to make specific reference to CPD, child protection, and basic Life support?**

Response: No. Reference to CPD is made in private dental standard 18.

**In relation to Regulations 14 Regulations 15 and 16, clarity was sought about whether contravention of these regulations were deemed an offence**

Response: The original intention was for concerns raised about a dentists' professional or clinical practise to be referred to the GDC for review. On this basis, Regulations 14,15,16 were not categorised as an offence. However, where a complaint has a focus on an issue of a regulatory nature, for example, complaints policy and procedures, these will need to be addressed by HIW. Consequently it has been decided to classify Regulations 14,15, 16 as offences. The categorisation of these Regulations as offences is consistent with the offences set out in the Private and Voluntary Health Care (Wales) Regulations 2002 for private doctors. Where there are concerns raised about a dentists' professional or clinical practise, this will usually be referred to the GDC for review - and this will form a key element of the Memorandum of Understanding between HIW and the GDC.

**In relation to Schedule 2 (5) is there a need to clarify that insurance includes membership of an appropriate and recognised professional indemnity society?**

Response: No. The GDC provides guidance on this matter

**The General Dental Council has asked whether including clinical dental technicians (and other registered dental care professionals) within regulation needs to be further reviewed given their current consultation on the scope of practise for dentists and associated dental care professionals.**

Response: It is proposed that clinical dental technicians be excluded from the Regulations until the outcome of the General Dental Council consultation. It is suggested that the Regulations be subject to further review in 12 months time. The Assembly Government's Chief Dental Officer has confirmed that the exclusion of clinical dental technicians, at this particular time, is not a high patient safety risk.

**Should treatment / injections for cosmetic purposes be incorporated in to the Regulations?**

Response: No. The GDC are currently consulting on the scope of practise for dentists and associated dental care professionals. The statutory registration of dental care professionals (DCPs) is a fundamental development in dentistry. It means that from July this year everyone involved in the clinical care of a patient must be registered with the GDC. The consultation includes a question as to whether Botox and Dermal fillers should be considered as dentistry and part of the registrants practise. This will be kept under review, should the administration of Botox and other substances for non-surgical cosmetic use be included as part of the 'practise' of a dentist by the GDC, once their current consultation has concluded.

**In relation to Regulation 23, should the proposed six months transition period be extended?**

Response: No. Given that the proposed coming into force date is January 2009 and that HIW will be carefully managing the process to operationalise the

Regulations, the proposed transition period of six months (i.e. the time in which fully completed applications for registration must be received by HIW following the Regulations coming into force) is considered to be sufficient.

**In relation to Regulation 14, the following insert is suggested at the end of the last sentence in sub- section 14(4): ....” to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.”**

This reflects Para 4.4 p. 45 of the Department of Health consultation *The future regulation health and adult social care in England: A consultation on the framework for the registration of health and adult social care*. In primary dental care, the Dental Reference Service has reported a range of poor decontamination practices and conditions in surgeries that place patients at risk of infection. Concerns about the risks of blood-borne infections have also grown. Research has demonstrated that infective agents may adhere to dental instruments and transfer infection if these instruments are reused (even if good decontamination practices are in place).

**It is suggested that EEC dentists who provide private dental services on a temporary and occasional basis be subject to regulation**

Given the potential risk to patient safety, it is proposed that EEC dentists who provide private dental services, on a temporary and occasional basis, be subject to regulation.

**Why has the decision been taken to register dental practitioners rather than the dental practice?**

Response: Registering dental practitioners rather than dental practices ensures that administrative bureaucracy is minimised – for example, those dental practitioners who provide both NHS funded dental treatment and private dental treatment need only provide a statement that they are complying with the Regulations and a statement that they are currently on an NHS Performers List, together with an enhanced criminal records certificate. Also, registering individual dental practitioners will enable HIW to track those dentists who move from practice to practice

**Is there a conflict / duplication of roles between the General Dental Council (GDC) and HIW?**

Response: No. The roles of HIW and the GDC are distinct. HIW, as the regulator of private and voluntary healthcare in Wales, undertakes inspections of registered persons to seek assurance on compliance with registration conditions. The GDC registers qualified professionals, sets standards of dental practice and conduct, assures the quality of dental education, keeps professionals up to date, and acts on complaints made by patients or information passed to them by other organisations. The GDC does not inspect dental practices to seek assurance on the quality of dental treatment. However, as part of its regulatory role HIW also seeks assurance on how complaints have been dealt with and can also deal with complaints passed to them by patients or other organisations, in the same way as the GDC. HIW and the GDC will be agreeing a Memorandum of Understanding to ensure that clinical / professional complaints and complaints of a regulatory nature are dealt with effectively.

**Will dental practitioners have a period of grace in which to submit applications for registration?**

Response: Yes. Applications for registration must be made within six months of the Regulations coming into force.

**Will the need to obtain an enhanced criminal records bureau check delay the registration process?**

Response: No. The CRB currently advise that they aim to process 90% of enhanced CRB applications within 4 weeks. However, this is dependent on receipt of an accurately completed and appropriately countersigned CRB application

**Why is a registration fee and an annual fee being charged?**

Response: The registration fee of £50 is a contribution towards Healthcare Inspectorate Wales (HIW) administrative and other costs associated with the registration process. The annual fee of £50 is a contribution towards the costs of regulation, including the inspection of private dental treatment, the preparation of inspection reports, the handling of any complaints and dealing with on-going registration related issues.

**Will the annual fee increase yearly?**

Response: It is not the intention to increase fees annually, but fees will be kept under regular review by HIW. Any fee increase will be kept to a minimum.

**Who will pay for the criminal records bureau check?**

Response: The dental practitioner will be responsible for paying for the criminal records bureau check.

**Will HIW staff be undertaking dental inspections?**

Response: No. HIW will be working with the Dental Reference Service (DRS). The intention is for the DRS to inspect, on behalf of HIW, private dental treatment at the same time as they undertake their NHS related practice visits. DRS will also undertake inspections of dental practitioners who provide wholly private dental treatment. This will ensure consistency and continuity of professional expertise across the NHS and private sector together with minimising the regulatory burden and inspection costs. HIW and the DRS will be agreeing a Memorandum of Understanding detailing this work.

**What are the offences under the Care Standards Act 2000?**

Response: It will be an offence:

- To provide private dental treatment without being registered with HIW
- To fail to comply with a condition of registration
- To breach a regulation which has been specified as an offence - Regulation 9,14,15, and 16.
- To make false statements in any application for registration or to vary conditions of registration that is misleading in a material way
- To fail to display a certificate of registration

Conviction of an offence will result in a fine not exceeding £2,500. Carrying on providing private dental treatment where the registration has been cancelled by HIW or where offence is second or subsequent conviction will attract a higher penalty.

HIW will only seek prosecution of a regulatory breach in very exceptional circumstances. Rather, any breaches to the regulations will be addressed in discussion with HIW and the GDC. This approach will be most effective in seeking

to encourage continuous improvement in the provision of private dental treatment and the improvement of clinical governance throughout primary dental care in Wales. The MoU between HIW and the GDC will also specify who will be responsible for taking forward actions in relation to specific issues. For example, it is envisaged that the GDC will take forward professional or clinical practise issues.

### **Can appeals be made against an offence?**

Response: Yes. Appeals against an offence can be made to the Care Standards Tribunal.

18. As a result of the consultation, the following amendments to the Regulations have been proposed

(a) Regulation 5 (2) (d) and (e) Applications for Registration has been inserted to specify that visiting EEA nationals who provide private dental services on a temporary and occasional basis will need to register with HIW.

(b) Regulation 5 (2) Applications for Registration has been amended to exclude the need for clinical dental technicians to register with HIW.

(c) Regulation 5 (2) Applications for Registration will be amended to include details of any condition imposed on his or her registration by the General Dental Council or his or her inclusion on a Performers List

(d) Regulation 8 Contents of Certificates has been amended to include details of the dental practitioner's home address or business address (address can be contacted by patients)

(e) Regulation 14 (1) (b) Quality of Treatment has been amended to exclude the words " provided as promptly as possible "

(f) Regulation 14 (5) Quality of Treatment has been inserted to ensure that reusable medical devices are handled safely and decontaminated effectively prior to re-use.

(g) Regulation 18 (c) Notice of Changes has been inserted to require the dental practitioner to notify the HIW of any changes in their contact and home address

(h) Regulation 19: Regulations 14,15,16 have been categorised as offences.

### **Post-Implementation Review**

19. The implementation of the Regulations is being carefully managed by HIW. Key milestones and timescales are being agreed to ensure that the registration process is operationalised effectively and that Memoranda of Understanding are in place with the key stakeholders (such as the General Dental Council and the Dental Reference Service) before the Regulations come into force in January 2009.

List of bodies / individuals consulted

Dental Practitioners and Clinical Dental Technicians registered with the General Dental Council

Local Health Boards Primary Care Leads

Local Health Boards Chief Executives

Local Health Boards Public Health Directors

Chief Officers of Community Health Councils Wales

Chief Executives National Health Trusts

National Public Health Service Regional Consultants/Directors of Dental Public Health

BDA, Director Wales

NHS Direct Wales Senior Managers

Deans and Senior Executives Dental Postgraduate Departments

Directors of Business Services Centres

General Dental Council

National Assembly for Wales, Assembly Members

**List of bodies / individuals who responded**

General Dental Council

British Dental Association Wales

Monmouth LHB

Denplan

National Public Health Service Wales

Gwent Local Dental Committee

Blaenau Gwent Local Health Board

Neath Port Talbot Local Health Board

Children's Commissioner for Wales

Community Health Councils in Wales

National Clinical Assessment Service Wales

North Wales Local Health Boards

Neath Port Talbot Community Health Council

Dental Practitioners - 16 responses