

**Registration under the Care Standards Act 2000**

**Guidance for new providers who are applying to register under the Private Dentistry (Wales) Regulations 2017**

 **September 2017**

Contents

[Introduction 3](#_Toc489287812)

[Registration Flowchart 4](#_Toc489287813)

[Stage 1: Pre-application 5](file:///U%3A%5CDefaultHome%5CObjects%5CHIW%20-%20Dental%20Practices%20-%20Application%20guidance%20-%20August%202017-e.docx#_Toc489287814)

[Stage 2: Application 12](file:///U%3A%5CDefaultHome%5CObjects%5CHIW%20-%20Dental%20Practices%20-%20Application%20guidance%20-%20August%202017-e.docx#_Toc489287815)

[Stage 3: Assessment 16](file:///U%3A%5CDefaultHome%5CObjects%5CHIW%20-%20Dental%20Practices%20-%20Application%20guidance%20-%20August%202017-e.docx#_Toc489287816)

[Stage 4: Receiving a decision 21](file:///U%3A%5CDefaultHome%5CObjects%5CHIW%20-%20Dental%20Practices%20-%20Application%20guidance%20-%20August%202017-e.docx#_Toc489287817)

[Stage 5: Registration 24](file:///U%3A%5CDefaultHome%5CObjects%5CHIW%20-%20Dental%20Practices%20-%20Application%20guidance%20-%20August%202017-e.docx#_Toc489287818)

Appendix A: Application Checklist…………………………………………………..……29

# Introduction

This guidance takes you through each stage of the application process for registration with HIW.

The ‘Application Checklist’ in the appendix lists the documentary evidence you need to submit during the application process. It is an offence to knowingly make a false declaration. This could render you liable to prosecution and could lead to the refusal of your application.

If you have any queries about this guidance or registration please contact us:

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# Registration Flowchart

# Stage 1: Pre-application

**Section 1: What to think about before making your application**

1. Regulations that apply to you
2. The service you will be providing
3. DBS checks
4. References
5. Policies and Procedures
6. Statement of Purpose
7. Patient Information Leaflet
8. The building

Stage 1 Section 1: What to think about before making your application

1. Regulations that apply to you

If a provider carries out a service that comes within the scope of registration as set out in the **Care Standards Act 2000** and **the Private Dentistry (Wales) Regulations 2017** they are required to be registered with HIW.

The Private Dentistry (Wales) Regulations 2017 define the regulatory roles and responsibilities as:

* Registered provider – an organisation, partnership or sole trader that will “carry on” i.e. carry out regulated services at a private dental practice
* Registered person – a person who can be the registered provider and/or the registered manager of a private dental practice and carries on and/or manages regulated services
* Registered manager – a person who is registered under Part 2 of the Care Standards Act 2000 and manages the regulated services at a private dental practice on a daily basis

Registration can be granted in the following ways:

1. **An organisation / body corporate (i.e. registered with Companies House) to carry on regulated activities.** The person accountable within the organisation/body corporate will be known as the responsible individual (RI) and **registration will be given to the registered provider to carry on regulated activities.**

To be registered as an organisation/body corporate, the RI must nominate a person to be the registered manager (RM). The RM must manage the regulated activities on a daily basis and demonstrate that they meet the criteria set out in Regulation 11 – Fitness of a Manager. **The RM will be registered separately to manage regulated activities on a daily basis**.

1. **An unincorporated association, other than a partnership to carry on regulated activities.** The person accountable within the unincorporated association will be known as the RI. **Registration will be given to the registered provider to carry on regulated activities. If possible a separate person should be nominated to be RM. The RM will be separately registered to manage regulated activities on a daily basis**

However, if it is not possible for two separate people to take on the role of RI and RM, then the same person can take on both roles as long as they manage the regulated activities on a daily basis and demonstrate that they meet the criteria set out in Regulation 11 – Fitness of a Manager. **This person will be registered to carry on and manage regulated activities.**

1. **A partnership that is registered with Companies House as an organisation / body corporate.** The partnership will be registered as the registered provider to **carry** on regulated activities with the partners as the responsible individuals. If possible a separate person should be nominated to be RM. **The RM will be separately registered to manage regulated activities on a daily basis**

However, if one of the RIs are also taking on the role of the RM they must be able to demonstrate that they are managing the regulated activities on a daily basis and demonstrate that they meet the criteria set out in Regulation 11 – Fitness of a Manager. **This person will be registered to carry on and manage regulated activities.**

1. **A partnership that is an unincorporated association, commonly referred to as an expense sharing partnership where two or more sole traders work together without registering as a partnership with Companies House.** Each partner will be registered individually as a registered provider to **carry on** regulated activities and will be known as the responsible individuals. This will also attract two registration fees. If possible, a separate person should be nominated to be RM. **The RM will be separately registered to manage regulated activities on a daily basis**

However, if it is not possible for two separate people to take on the role of RI and RM, then the same person can take on both roles as long as they manage the regulated activities on a daily basis and demonstrate that they meet the criteria set out in Regulation 11 – Fitness of a Manager. **This person will be registered to carry on and manage regulated activities.**

**The National Minimum Standards (NMS)**

The NMS are a tool for providers to use. They contain guidance on what applicants are expected to have in place at registration and ongoing.

**Other legislation**

You must also ensure that your service complies with wider laws, for example you must observe relevant health and safety requirements.

1. The service you will be providing

You need to state on your application form the service you wish to provide. The main categories are private dental treatment, private and NHS dental treatment, private dental treatment using a Class 3B or Class 4 laser product for dental procedures only and private direct access dental treatment

If you are providing laser services using a Class 3B or Class 4 laser product for dental procedures, you will need to appoint a Laser Protection Adviser (LPA) who can help with your application. You also need to have in place local rules for the laser and treatment protocols for all treatments you are looking to provide.

If you are using a Class 3B or Class 4 laser product for any other purposes, you will need to register separately under the Independent Healthcare (Wales) Regulations 2011.

1. Disclosure and Barring Service (DBS) checks

All registered persons must have an enhanced DBS check issued within the last three years. We can also accept if you have signed up to the DBS Update Service.

If you need to apply for a DBS, you can request a form by calling 0300 062 8163 or emailing HiwRegistration@gov.wales. Guidance on completing the DBS form can be found at [www.homeoffice.gov.uk/dbs](http://www.homeoffice.gov.uk/dbs)

You must send the completed DBS application form and supporting documents to HIW with a payment by cheque or card for £44.00 to cover the cost of the check.

**Please note**: HIW can only verify original documentation – photocopies cannot be accepted.

1. References

All registered managers need to provide up to 2 personal references. Template reference forms are available on HIW’s website [www.hiw.org.uk](http://www.hiw.org.uk)

1. Policies and procedures

You need to write a set of policies and procedures. Regulation 8 of the Private Dentistry (Wales) Regulations 2017 sets out the policies and procedures that need to be in place for your service.

You will need to provide an index of your policies and procedures (a template is available on our website) when applying to register and we will either request a sample of polices and procedures as part of the registration process or request to see the full policies and procedures if we carry out a site visit.

1. Statement of Purpose

Regulation 5 and Schedule 1 of the Private Dentistry (Wales) Regulations 2017 set out the information required in your Statement of Purpose.

Every service provider is required by law to have a Statement of Purpose and it should include specific details about your service, what treatments are provided, to who (age), by whom and any equipment used.

Your Statement of Purpose **must** include:

* **The aims and objectives of your service** – explain the goals that your service has set for itself and include the outcomes or results that you will use to measure its success. You should also try to describe the specific impact you intend to have on the people who use your services and what benefits they can expect to experience as a result of accessing the services you provide.
* **Registered Provider details -** name, address and contact details. If you are an organisation (such as a company), you will need to give the details of the company’s registered office and details of the responsible individual and their relevant experience and qualifications.
* **Registered Manager details -** full name, contact address (if different from the location address), telephone number and email address.
* **Information about staff -** details of the number of staff employed to work in the practice. You will also need to state their relevant qualifications and relevant experience. Where you have part time staff you will need to state the number of whole time equivalents.
* **Services, Treatments and Facilities -** details of the services, treatments and facilities you intend providing, the indicative charges payable and how these will be provided referring to both the equipment and staff with the specialist skills to provide these. Describe the type of needs that the people who will use your services will have. Give details of specific health needs that you aim to meet. You should not include any personal or confidential details about individuals in the Statement of Purpose.
* **Patient views -** describe how you will seek patient views in order to monitor the quality of the services you provide and how you intend to use this information.
* **Practice opening hours and information on out of hours care -** provide the practice opening hours and information for patients who require urgent care or treatment out of hours.
* **Complaints -** explain how a patient can lodge a complaint and set out the timescales for responding. You should ensure that your policy meets the requirements of **Regulation 21** of the Private Dentistry (Wales) Regulations 2017, which includes the need to include contact details for HIW in your policy.
* **Privacy & Dignity -** describe how you will respect the privacy and dignity of your patients.
* **Date -** the date on which the Statement of Purpose was agreed.

If you do not have a Statement of Purpose available when we request it, this may result in the refusal of your application, or once registered, HIW taking enforcement action against you.

We will use your Statement of Purpose to help us reach judgements about whether your service is meeting the relevant standards. **The Statement of Purpose should therefore include enough detail for a reader to get a clear picture about the type of service you provide and the people who use your service.**

You are required to review your Statement of Purpose at least once a year, notify us of any amendments within 28 days of the review and you must provide treatments and services in accordance with your Statement of Purpose.

We will refer to your Statement of Purpose when we undertake an inspection to ensure that the services and treatment you are providing are as described in your Statement of Purpose.

There is a template on our website for the Statement of Purpose as a guide only. If you already have a Statement of Purpose that **meets all the requirements** you do not need to rewrite it using the template.

1. Patient Information Leaflet

Regulation 6 and Schedule 2 of the Private Dentistry (Wales) Regulations 2017 set out the information required in your Patient Information Leaflet.

Every service provider is required by law to have a Patient Information Leaflet and it should provide information for patients on the service they are to receive. The guide should be provided to every patient and any person acting on behalf of a patient.

By law the Patient Information Leaflet must include:

* a summary of the Statement of Purpose, including
	+ - * + *the name address and contact details of the registered provider and registered manager,*
				+ *the names of all dentists and dental care professionals employed,*
				+ *treatments facilities and all other services provided*
				+ *practice opening hours and arrangements for patients needing urgent care or treatment out of hours*
				+ *arrangements for dealing with patients who are violent or abusive to staff*
				+ *arrangements for dealing with complaints as per Regulation 21*
* relevant experience and qualifications of all dentists and dental care professionals employed
* the arrangements made for seeking patients’ views about the quality of services provided
* the arrangements for the appropriate development and training of employees
* the address and telephone number for each of the premises used for the purposes of carrying on a dental practice by the registered provider
* the arrangements for access to the practice
* information on the rights and responsibilities of patients including keeping appointments
* the name of persons who have access to patient information and the patients’ rights in relation to disclosure of such information

There is a template on our website for the Patient Information Leaflet as a guide only. If you already have a Patient Information Leaflet that **meets all the requirements** you do not need to rewrite it using the template.

1. The building

Regulation 22 of the Private Dentistry (Wales) Regulations 2017 sets out the assessment HIW will carry out to demonstrate fitness of the premises carry on the services.

We will assess your application based upon the readiness of the service to meet patients’ needs.

You must ensure that premises:

* Provide a clean and safe environment
* Are of sound construction and kept in a good state of repair externally and internally
* Are of a suitable size and layout for the purposes for which they are being used and are suitably equipped and furnished
* Have facilities for employees for the purposes of changing
* Have storage facilities

Regulation 22 5(b)of the Private Dentistry (Wales) Regulations 2017 states that the registered person must ensure that the requirements of the Regulatory Reform (Fire Safety) Order 2005 are complied with. If this Order does note apply to your dental practice the registered person must meet the measures listed in Regulation 22
(4)

# Stage 2: Application

Stage 2 Section 1: Completing your application form

**Section 1: Completing your application form**

1. Filling in your application form

**Section 2: Submitting your application**

1. Incomplete applications or missing information
2. Changing your application after submission
3. Filling in your application form

HIW would prefer this form to be completed electronically and it is available at [www.hiw.org.uk](http://www.hiw.org.uk). However, HIW can only accept wet signatures in Section 6 for audit purposes when practice up financial accounts with the Welsh Government.

If you cannot access our form electronically, and it is completed as a hard copy, please use block capitals. If you need hard copies of the form please contact us and we can post them to you.

You can use this section of the guidance in conjunction with your application form as you fill it in.

***Section 1: Application details***

**Section 1.1 refers to an organisation / registered provider.** This is the organisation, partnership or sole trader that is being registered to **carry on** regulated services at a private dental practice i.e. it may not be the name of the dental practice, but the name of an establishment or person that has financial control over the dental practice**. This section should be completed in all scenarios.**

**Section 1.2 refers to a responsible individual.** This is a person named by an organisation/registered provider as responsible for supervising the management of a private dental practice.

This person could be a company director or an officer within the organisation/registered provider that has responsibility for overseeing the management of a private dental practice.

**This section should be completed if a dental practice is:**

* an organisation/registered provider registered with Companies House.
* a sole trader. i.e. the same owner of, and dentist working at, a dental practice then this person would fulfil the role of responsible individual and registered manager and should complete all questions of the application form
* a partnership. All partners would be classed as responsible individuals.

**PLEASE NOTE**: Each partner must complete the following sections of the application form:

* + 1.1 – organisation/registered provider details
	+ 1.2 – responsible individual details
	+ 3.1 – DBS details
	+ 3.2 and 3.3 – Rehabilitation of Offenders Act 1974
	+ 3.4 – refused applications and cancellations
	+ 3.7 – responsible individual medical history
	+ 6 – application declaration

**Section 1.3 refers to a registered manager.** This is the person who has day to day responsibility for managing the dental practice. **This section must be completed in all scenarios**.

The regulations do not stipulate who can hold this position however they must be able to demonstrate that they can meet the criteria set out in Regulation 11 – Fitness of a Manager. This may be a practice manager, dental care professional or a dentist.

If there is more than one registered manager, each manager should complete all sections of an application form.

***The term “registered person”*** is used in the regulations to refer to the registered manager and/or the registered provider without needing to list both terms.

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***Section 2: Regulated service(s)***

This section asks that you specify the service type you are registering according to the Regulations. It also asks more specific questions about the practice environment and the financial viability of the registered provider (see Stage 3 Section 2 of this guidance for more details).

***Section 3: Personnel information***

This section asks for further details about your previous registration history, employment history, medical history (see Stage 3 Section 3 of this guidance for more details), DBS checks and your professional registration.

***Section 4: Equality, diversity and human rights***

HIW must understand **how** you will ensure that human rights, equality and diversity needs are addressed in your practice and not that your practice has an equality policy in place.

***Section 5: Class 3B or Class 4 laser***

This section asks for details of any class 3B or class 4 laser products being used to provide dental treatments at the practice and the professional support you have employed.

***Section 6: Application declaration***

This section asks for you to sign and date the form declaring that the information you have provided is accurate. To knowingly make a false or untrue declaration is an offence under Section 27 of the Care Standards Act 2000. Please ensure that all persons named in Section 1 have signed the authorising signature section. Details of where to send the application are also included in this section.

**Other information to include with your application**

You need to provide the supporting information (as specified in the Application Checklist in the Appendix of this guidance) with your completed application form.

You must also give us information about other businesses that are carried on in the same premises as your service. This information needs to detail where you have shared use of premises and services. For example, entrance areas, water, electricity and gas, and what your responsibilities are for contracts and maintenance.

If the business is another provider and you have any interests or management responsibilities for the company, you should include these in the form.

Stage 2 Section 2: Submitting your application

If you have completed your application electronically, please remember that HIW can only accept wet signatures in Section 6 for audit purposes when setting up financial accounts with the Welsh Government.

If you have scanning facilities you can provide a scanned version of your application form and email it to HIWRegistration@gov.wales or alternatively, if you are using hard copies of our forms post them, using the address shown in the introduction section of this guidance.

1. Incomplete applications or missing information

We cannot process incomplete applications. Incomplete applications will be rejected and returned.

If your application is rejected because it is **incomplete,** we will endeavour to let you know what information was missing to enable you to resubmit it should you wish.

1. Changing your application after submission

If you need to amend your application, you will have to confirm this in writing and we will tell you if your amendment can be accepted.

Amendments will cause delay and may mean that we are not able to process your application within 16 weeks of accepting a fully completed application.

In addition, if you make changes to your application we may ask for further information. If you fail to provide the required additional information within the required deadline, HIW may refuse to grant the application.

If the changes to the application are substantial, you will have to make a new application.

# Stage 3: Assessment

**Section 1 – How we assess your application**

1. The assessment process

**Section 2 - Financial assessment**

1. Question on administration and receivership
2. Declaration about financial viability

**Section 3 - Medical assessment**

1. Declaration about physical and mental health

**Section 4 - Professional assessment**

1. Regulatory requirements
2. Personal / Professional references
3. Registered persons ‘fitness to manage and/or carry on’ interview

Stage 3 Section 1 – How we assess your application

1. The assessment process

There are 3 stages to our assessment process and we aim to complete all registrations within 16 weeks of **accepting a fully completed application**.

***On receipt*** of an application we will check that, as a minimum, the following information has been received with an application form:

* Statement of Purpose
* Patient Information Leaflet
* Up to 2 personal references (for registered manager(s))
* Policies and procedures index
* Confirmation that an enhanced DBS check has been carried out or is in the process of being carried out for registered persons
* For lasers only – a Laser Protection Adviser (LPA) report, signed local rules and treatment protocols.

**Please note**: we will not check the content of the documents at this stage but will determine an application is complete and able to be discussed at an initial panel meeting if you have provided the documents listed above.

If any of the documents listed above are missing we will contact you to request the missing information. If you do not provide the missing information we will return your application as incomplete and you will need to re-apply for registration once you are able to provide the required documentation.

It is also at this stage that we will check if there is any information you have previously provided for your registration as an individual dentist that can be used as documentary evidence to support your dental practice application.

The ***first stage, following receipt of a fully completed application,*** consists of an initial panel meeting where we discuss:

* The detail of the information provided to ensure it is in line with regulations and standards.
* The outcome of references and DBS checks provided.

**Please note**: if a DBS check is returned with any listed offences we will conduct an additional DBS interview with you.

If required, following this initial panel meeting, we will contact you to request the additional documentary evidence listed below (if not already available / provided):

1. a copy of the responsible person’s birth certificate
2. certificates or other suitable evidence of professional or technical qualifications of the responsible person and registered manager
3. copies of the last two annual reports (if practice is body corporate)
4. a copy of the last annual accounts
5. a copy of the certificate(s) of liability insurance

We may also request additional details that may need to be added to your regulatory documents.

If you fail to provide the required additional information within 16 weeks of the original submission of your application, HIW may refuse to grant your application

We will also contact you to advise you when your application has moved to the next stage of the assessment process.

The ***second stage*** may consist of a pre-registration site visit and a registered manager ‘fitness to practice’ interview. During the transition period this will be determined on a case by case basis.

If required, at the pre-registration site visit we assess:

* The readiness and suitability of your premises including environmental and health and safety checks.
* The full policies and procedures you have in place.

At this stage we will also carry out the registered manager ‘fitness to practice’ interview. This may be during the site visit or we may invite you to attend our office in Merthyr Tydfil.

The ***third stage*** consists of a final panel meeting to make a decision regarding your application for registration, based on:

* An assessment of all the evidence and information provided in your application and if applicable evidence from the pre-registration site visit and interview

Stage 3 Section 2 – Financial Assessment

Regulation 24 of the Private Dentistry (Wales) Regulations 2017 requires you to take all reasonable steps to ensure financial viability. You must make sure you have considered how you are going to finance the practice. This is to ensure that service users will have continuity of care and treatment should we register your service.

1. Question on administration and receivership

The information you provide for this section in the application form will be judged with the supporting evidence on your ability to carry out or manage a practice. You will be given the opportunity to discuss the details fully if required.

1. Declaration about financial viability

You must declare that you take all reasonable steps to remain financially viable in order to achieve your aims and objectives as set out in your statement of purpose. Your declaration will be completed by ticking a box on the application form, either ‘yes’ or ‘no’.

In considering whether you will be financially viable, you are strongly advised to have put together a business plan.

Stage 3 Section 3 – Medical Assessment

1. Medical declaration

You must declare if you have any physical and/or mental health condition which may affect your ability to carry on or manage the practice. Your declaration will be completed by ticking a box on the application form, either ‘yes’ or ‘no’.

You must consider whether you have an illness or medical condition that could put yourself or others at risk when providing services. (Reference to this can be found in Regulation 9 of the Private Dentistry (Wales) Regulations 2017).

If the information provided in your application form states that you have a condition that could affect your ability to carry out your role we will discuss this with you either at the interview stage or prior to this. We will ask you to tell us about any reasonable adjustments that you have put in place to enable you to do your job and will take these into account.

If we are not confident that you are medically well enough to be a registered person, we may refuse your application. You have the right to appeal against this. We will also consider any second opinion that you may wish to obtain.

Stage 3 Section 4 – Professional assessment

1. Regulatory Requirements

Regulations 9, 10, 11 and 12 of the Private Dentistry (Wales) Regulations 2017 outlines the requirements relating to registered managers’ ‘fitness’.

This includes an assessment of whether the person:

* **‘Is of suitable integrity and good character’.** We assess this through the information provided in your application form, the DBS check, references and interview.
* **‘Has the qualifications, skills and experience to manage the practice’.** We assess this through interview, references and the application form which require you to submit your complete employment history for the past 15 years (or your full career if shorter). You must provide us with a written explanation of all gaps between employment.
* **‘Is physically and mentally fit to manage the practice’.** We assess this through the information provided in your application form and interview.
1. Personal / Professional References

You need to submit up to two personal/professional references with your application (a form can be found on our website). The referees must be able to comment on your competence to manage/carry on the practice and should not be related to you. One of these referees should have been your employer for at least 3 months however where this is not possible an explanation of why this is the case should be provided. We will contact your personal/professional referee if we require any further information.

1. Registered person(s) ‘fitness to manage and/or carry on’ interview

On receipt of a completed application we will send you a questionnaire to fill in, which asks about the Regulations and your roles and responsibilities. We will address any points relating to the Regulations where clarification is needed.

We may then conduct an interview on the same day as a site visit or invite you to attend our offices in Merthyr Tydfil. Two HIW staff will conduct the interview asking you questions relating to your skills, knowledge and experience in the field you’ll be working in and about what you have written in the application form or your plans for the service.

# Stage 4: Receiving a decision

Stage 4 Section 1 – Timescales

**Section 1 – Timescales**

1. When you can expect an outcome

**Section 2 – Receiving a decision**

1. Notice of Proposal (NoP)
2. Notice of Decision (NoD)
3. Appeals
4. When you can expect an outcome

We aim to make a decision on all new providers within 16 weeks of accepting a fully completed application to the date that the NoD is served.

Please note that the 16 week countdown begins when we receive all the information requested so that we can move onto the assessment stages. This therefore depends on you submitting full and correct information with your application.

This timescale will be longer if:

* we request additional information but that information has not been returned to us within 5 working days;
* there is a change to an application or other delays which are beyond our control (these include slippage in completion dates for changes in ownership and premises not being ready);
* we have to carry out a site visit or interview applicants more than once, due to concerns identified as part of our assessment;
* we have significant concerns regarding the provider’s operation or if there is enforcement action that could impact on any necessary decision to vary registration;
* we refuse registration and an appeal is made against that decision.

Stage 4 Section 2 – Receiving a decision

1. Notice of Proposal (NoP)

When all stages of assessment have been completed, we will issue you with a (NoP). This is a legal notice and it will either state that we propose to:

* Register you without conditions.
* Register you with conditions.
* Refuse your application to register.

You have 28 days to make representations to us to appeal the Notice or any of the conditions listed on it. If we do not receive representations within this time frame we will continue to issue the NoD and will assume no representations will be made. Should you agree with the Notice and wish to speed up the process of registration you are able to sign, date and return a slip to us relinquishing your right to appeal.

A condition may be attached to your registration that:

* Restricts your regulated activity. A typical example of this is restricting the age range you are able to treat, for example, the NoP may state that you can not treat people between the ages of 6 and 13.
* States what types of services you are permitted to provide. For example, the NoP may state that you can provide diagnostic, surgical procedures (no cardiac surgery) or in the case of laser services will state the specific lasers and treatments you are permitted to carry out.
1. Notice of Decision (NoD)

When the NoP has elapsed (after 28 days) or you have signed, dated and returned a slip to us us relinquishing your right to appeal we will issue you with a NoD. This confirms that we have made a decision about the status of your registration. In the same way as the NoP, you have 28 days to make representations, allow the Notice to elapse or to sign, date and return your acceptance to us.

On receipt of your signed slip from the NoD or after 28 days have elapsed from the date on your NoD you are registered under the Care Standards Act 2000.

1. Appeals

You can make representations to us about any proposal we make in relation to your application to register.

We may propose to refuse to register you, or propose to register you subject to conditions. If you disagree with the proposal, the address for any representation is available in the Notice sent to you.

Following the NoP, if we do not uphold your representations, but continue to confirm our proposal through a NoD, you can appeal against our decision to an independent tribunal. In this situation, HIW will provide information about the tribunal upon request.

# Stage 5: Registration

**Section 1 - HIW’s commitments to you when registered**

1. Certificates
2. Website and logo
3. Inspections

**Section 2 - Your responsibilities when registered**

1. Keeping your service compliant with the Regulations
2. Informing us of changes
3. Reportable incidents
4. Annual Fees
5. Registered Manager responsibilities
6. Providing a service when not registered.

Stage 5 Section 1 – HIW’s commitments to you when registered

1. Certificates

We will issue certificates in the post for the whole provider registration. Each Registered Manager also receives a separate certificate. Certificates of registration must be displayed in a visible place in your practice.

1. Website and Logo

When you are registered with us, we will add details of your service to our website. This means that members of the public will be able to identify you as a registered provider of services.

With our permission, you can use our logo in your promotional materials as a quick way to show that you are registered with us. You will need to complete a form to use our logo which we can provide on request.

1. Inspections

HIW carries out regular announced and unannounced inspections of registered services to ensure the service continues to comply with the requirements set out within the Care Standards Act 2000 and supporting legislation. HIW’s Inspection team will provide you with a report from the inspection and will give you feedback about your service, asking you to make improvements where needed. If we find that you are not complying with the Regulations we could take enforcement action.

Stage 5 Section 2 – Your responsibilities when registered

1. Keeping your service compliant with the Regulations

You are responsible for ensuring that your practice continues to meet the requirements of the Care Standards Act 2000 and supporting legislation.

It will be usual practice for HIW to bring any non-compliance to the specific attention of the individuals concerned, providing an opportunity for relevant remedial action to be taken within a specific timescale.

If the non-compliance is of a serious nature, HIW may consider it appropriate to impose certain conditions on your service or cancel registration of your service altogether meaning that your service must cease operating. HIW may also take action by way of a prosecution which could result in a fine and / or imprisonment.

1. Informing us of changes

**You are responsible for informing HIW of any changes to the services that you provide.**

If, at any point in the future following your registration with HIW, you want to vary the terms of your registration or change any conditions listed on your certificate of registration, you will need to submit an application to do this.

You would not legally be entitled to carry out the changes until we have agreed your application. You would receive a Notice of Proposal and Notice of Decision in the same way as your initial registration.

**Fees to vary a condition of registration**

If you wish to vary a condition of registration you will need to pay a fee. The table below sets out these fees. You should submit the application to HIW and we will contact you to request the fee. We will include information on how to make the payment.

**Minor variation**

A minor variation is a variation of conditions where it is not necessary for HIW to inspect the practice in order to determine the application.

The following are examples where an inspection would not normally be considered necessary – however each application will be considered on its own merits:

* Cessation of a type of treatment or service.
* Minor alterations to accommodation.
* A new Class 3B or Class 4 laser product to carry out similar treatments to those already registered.

**Major variation**

A major variation is a variation of conditions where HIW consider it necessary to inspect the practice in order to determine the application.

It will often be an application which changes the purpose for which registration was originally granted. The following are examples where an inspection may be considered necessary – however each application will be considered on its own merits:

* Extension of the service into newly built accommodation.
* Changes to a service that requires new equipment/staffing.
* Alterations to existing patient accommodation that involves structural alteration such as
	+ removing walls,
	+ changing fire evacuation routes,
	+ changing the use of rooms used by patients,
	+ changes to accommodation where invasive treatments are provided.

|  |  |
| --- | --- |
| **Type of variation** | **Fee** |
| Minor  | £250 |
| Major | £500 |

**Fee to remove a condition of registration**

If you wish to remove a condition of registration you will need to submit an application. HIW will consider it and request the £50 fee. Details of how to make the payment will be included.

1. Reportable Incidents

Regulations 25 - 30 of the Private Dentistry (Wales) Regulations 2017 state that you must inform HIW if any of the following events occur:

* + Death of a patient;
	+ Serious injury to a patient;
	+ Outbreak of any infectious disease;
	+ Allegation of misconduct against a member of staff;
	+ When a registered person proposes to be absent from the practice for more than 28 days consecutively;
	+ Notification of offences
	+ Notice of changes
	+ Appointment of liquidators
	+ Death of a registered person

Notifiable events guidance and forms are available at [www.hiw.org.uk](http://www.hiw.org.uk)

1. Annual Fees

All private dental practices have to pay an annual fee to remain registered. Fees are payable:

* When applying to vary any condition of registration
* When applying to remove a condition of registration
* Annually to maintain registration

The annual fee is £500 or £300 if the practice consists of no more than one dentist and that dentist provides private and NHS dental services.

Your annual fee is due one month after the date of registration (pro rata for the remaining months of the financial year) and annually on 1 April thereafter. You will be notified that your annual fee is due by way of an invoice. This will provide details of the amount you will be required to pay, the date it must be paid by and how you can pay it. You should not pay your fee until you have received the invoice.

If you do not pay your annual fee by the due date, HIW will issue a Notice of Proposal to cancel your registration. HIW may also choose to recover the fee as a civil debt.

If you apply to cancel your registration you may be entitled to a refund. The refund of annual fees is covered by Regulation 33, Schedule 5, 5. (2) which states that:

* The refund will be no more than 75% of the annual fee.
* Any refund will be calculated by how many complete quarters remain of the registration year (calculated form the date of payment of the annual fee).
* A quarter of the year means a period of three consecutive months.
* In calculating how many quarters of the year remain, no account is to be taken of the calendar month in which the application to cancel is received.
1. Registered Manager responsibilities

Please note that Registered Managers are responsible for their own registration, including applying to register and changing the details of their registration. **When a Registered Manager leaves their post it is their responsibility (not the provider’s) to notify us.** An application to cancel their registration must be submitted. The consequence of not cancelling their registration is that they remain legally liable for the service.

1. Providing a service when not registered

Any person who carries on or manages a practice which provides a relevant service without being registered commits an offence under section 11(1) of the Care Standards Act 2000.

From time to time, HIW receives information suggesting services may be operating outside registration. This results in HIW taking action to investigate. HIW has powers under Section 31(2) of the Care Standards Act 2000 to enter and inspect any premises which are used, or which it has reasonable cause to believe are being used, to provide services that are required to be registered.

Where a service is being provided without being registered HIW will take enforcement action. This may range from a requirement to cease provision of the service until registration has been achieved but may also result in prosecution where conviction may lead to a fine and / or imprisonment.

**Appendix A: Application Checklist**

There is only one application form to complete if you are registering for the first time with Healthcare Inspectorate Wales and the checklist below is the **documentation that will be required at different stages of the assessment process** in addition to a completed and signed application form.

|  |
| --- |
| **For all applications submitted to HIW** |
| * Statement of Purpose
 |
| * Patient Information Leaflet
 |
| * Policies and procedures index
 |
| * Copy of last annual accounts for private dental practices
 |
| * Copy of last two years annual reports of the applicant is a body corporate. *Where the organisation is a subsidiary of a holding company, the name and address of the registered or principal office and the last two annual accounts (if any) of the holding company and of any other subsidiary of the holding company*
 |
| * Either an enhanced DBS certificate issued within the last 3 years for the responsible person and registered manager or a completed DBS application form (with supporting documents), or a disclosure certificate for the update service, plus the relevant fee for the registered manager
 |
| * Up to 2 personal / professional references for the registered manager
 |
| * Copy of birth certificate for responsible person and registered manager
 |
| * Certificate(s) for professional or technical qualifications for the responsible person and registered manager
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| **In addition to the above, laser applications must also include the following additional information** |
| * Evidence that you have employed a Laser Protection Advisor (LPA)
 |
| * Professional protocol drawn up by a trained and experienced dentist or dental care professional to demonstrate the local rules and treatment procedures
 |
| * Register of each occasion the laser product has been used (to include the name of the patient, the name of the person using the system and the date on which the system was used)
 |
| * Certificates of appropriate training for all product users i.e. Core of Knowledge
 |