

Registration under the Care Standards Act 2000

**Guidance for new providers who
are applying to register under the
Independent Health Care (Wales)
Regulations 2011**

September 2017

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Introduction

This guidance is for all providers who need to be registered under the Care Standards Act 2000 and who will be applying for registration with Healthcare Inspectorate Wales (HIW).

This guidance takes you through each stage of the application process for registration with HIW. **Please note:** services offering IPL and/or laser treatments should pay particular attention to the highlighted yellow boxes throughout the guidance which outline specific information for these services.

The 'Application Checklist' in the appendix lists everything you need to submit with your application. 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:

Registration Team
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ

Tel. 0300 062 8163
Email. HiwRegistration@gov.wales

Registration Flow Chart

Stage 1: Pre-application

Review Regulations and prepare application (p 5-10)



Stage 2: Application

Complete and submit application (p 11-15)



Stage 3: Assessment

HIW assesses application (p 16-20)



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Stage 1: Pre-application

Section 1: What to think about before making your application

- A. Regulations that apply to you
- B. The service you will be providing
- C. DBS checks
- D. References
- E. Policies and Procedures
- F. Statement of Purpose
- G. Patient Guide
- H. The building

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

A. 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 Independent Health Care (Wales) Regulations 2011** they are required to be registered with HIW.

Registration can be granted in the following ways:

- a. **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.**

- b. 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.**

The National Minimum Standards (NMS)

The NMS are a tool for providers to use. They contain guidance on what you need to have in place for registration to be granted and also what you need to do following registration. You will need to familiarise yourself with this before you can declare full compliance in your application form.

Other legislation

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

Services Offering IPL and Laser treatments

Please note that we need to see specific information in relation to planning permission for those services offering IPL and laser treatments. See Appendix A - Application Checklist for further details.

B. The service you will be providing

You need to state on your application form the service you wish to provide. There are three main categories - Independent Hospital; Independent Clinic and Independent Medical Agency. For the full definitions, please see the Regulations <http://www.legislation.gov.uk/wsi/2011/734/contents/made>

C. Disclosure and Barring Service (DBS) checks

You need to apply for DBS certificates for all relevant individuals, including anyone who will be a Registered Manager (RM).

All RMs applying to register with HIW require a valid enhanced DBS, **countersigned by HIW**, and issued within the last three years.

If you have signed up to the DBS Update Service we can accept this, but will need to see the original certificate.

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/db

You must send the completed DBS application form and supporting documents to with a payment by cheque or card for £44.00 (which includes postal costs) to cover the cost of the check.

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

D. References

Medical, personal and financial references are required for all relevant individuals. The Application Checklist in the appendix lists all references required. Template reference forms are available on HIW's website www.hiw.org.uk

E. Policies and procedures

You need to write a set of policies and procedures. Regulation 9 of the Independent Health Care (Wales) Regulations 2011 sets out the policies and procedures that need to be in place for your service (<http://www.legislation.gov.uk/wsi/2011/734/contents/made>)

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 request to see the full policies and procedures when we carry out our site visit. We may also request a sample of policies and procedures as part of the registration process.

F. Statement of Purpose

Regulation 6 and Schedule 1 of the Independent Health Care (Wales) Regulations 2011 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 establishment or agency. 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 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.
- **Arrangements for visiting** - provide details of the arrangements for contact between any in-patients and their relatives, friends and representatives including where applicable any limitations on visiting 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 24** of the Independent Health Care (Wales) 2011 Regulations.
- **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 at least 28 days before the changes are due to take effect 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.

G. Patient Guide

Regulation 7 of the Independent Health Care (Wales) Regulations 2011 set out the information required in your Patient Guide.

Every service provider is required by law to have a patient guide 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 guide must include:

- **a summary of the Statement of Purpose** – aims/ objectives
- **the terms and conditions of services to be provided to patients, including full information on charges** – explain what your services involve, how long treatments can last and what the amounts and methods of payment are for all aspects of treatments.
- **a standard form of contract for services and facilities provided** – explain how services will be provided and what additional facilities are available
- **a summary of the complaints procedure** – the details contained in your Statement of Purpose can be used.
- **a summary of the views of patients and others** - for new establishments or agencies this will not be available. This information should be added to the Patient Guide when the document is reviewed for the first time.
- **an address and telephone number of the appropriate office of the registration authority** - details for Healthcare Inspectorate Wales can be found on page 3 of this guidance.
- **information on how to obtain a copy of the most recent inspection report prepared by the registration authority** – include a link to HIW's website and inform patients that when your organisation has been inspected reports will be available here.

There is a template on our website for the Patient Guide, as a guide only. If you already have a Patient Guide that meets all of the requirements, you do not need to re-write it using the template.

H. The building

HIW will assess your application to demonstrate fitness of the premises to carry out the services and to meet patients' needs. You should ensure that everything is in place before commencing your service.

I am registering to provide laser / IPL services - what additional preparation will I have to do?

You must appoint a Laser Protection Adviser (LPA) to help with your application. You also need to have in place local rules for the machine and treatment protocols (written by a practicing GMC registered professional) for all treatments you are looking to provide. More information on this can be found within the National Minimum Standards for Independent Health Care in Wales - a copy of which is at www.hiw.org.uk.

Stage 2: Application

Section 1: Completing your application form

A. Filling in your application form

Section 2: Submitting your application

B. Incomplete applications or missing information

C. Changing your application after submission

Section 3: Registration fees

D. Fees to pay

Stage 2 Section 1: Completing your application form

A. Filling in your application form

HIW would prefer this form to be completed electronically and it is available at www.hiw.org.uk.

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.

Individuals and Organisations – step by step guide

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

Section 1: Application details

This section asks for the basic information about the applicant including contact details and details of the company (if an organisation).

Section 2: Regulated Service(s)

This section asks that you specify the service type that you are registering according to the Regulations. It also asks more specific questions about the setting's environment and the financial viability.

Section 3: Personnel Information

This section asks for further details about your previous registration history, employment history, medical history, DBS checks and any professional registration.

Section 4: Equality, diversity and human rights

This section asks **how** you will ensure that:

- human rights and equality and diversity needs are addressed in your service.
- the capacity to respond to diverse needs is developed.
- independence and choice is promoted.
- human rights and diversity issues are equal in importance to other issues.
- information is accessible to people who use it.
- your staff understand and respect the beliefs and customs of people's faith and understand their responsibilities under equalities legislation.

Section 5: Class 3B or Class 4 laser and /or Intense Pulsed Light

This section asks for details of any class 3B laser, class 4 laser or Intense Pulsed Light (IPL) products being used to provide treatments at the establishment 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.

Other information to include with your application

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

You should 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.

B. Incomplete applications or missing information

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

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

C. 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 12 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 12 weeks of the original submission of your application, HIW may refuse to grant the application.

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

Stage 2 Section 3: Registration fees

D. Fees to pay

Usually a registration fee is payable with your application unless you qualify for an exemption.

The amount to pay is not determined by Healthcare Inspectorate Wales, but is set out in the Independent Health Care (Fees) (Wales) Regulations 2011 – please see Table 1 below.

Fees are payable:

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

You will not have to pay a fee:

- If you are a person carrying on or managing, or applying to carry on or manage a Hospice.
- If you are the provider of an establishment or agency and you are a charity **and** the only services provided by that charity are free **and** the charity's services are not commissioned by the NHS or a local authority. *NB: this exception does not apply to managers of establishments or agencies run by charities that fulfil this criteria.*

Where an establishment or agency falls within more than one of the categories listed, only one fee is payable, this will be the higher fee.

If there is more than one individual applying to be registered, each individual needs to pay a fee.

Payment can be made by debit/credit card by completing the payment form on HIW's website or by calling 0300 062 8163 with the card details. Alternatively you can send a cheque made payable to 'Welsh Government'.

Table 1 – registration fees

Independent Hospitals

Category	Application fee for registration as a Provider	Application fee for registration as a Manager
Non-acute hospital	£1,500	£100
Acute Hospital	£2,500	£100
Mental Health Hospital	£2,500	£100
Termination of Pregnancy Hospital	£750	£100
Maternity Hospital	£1,500	£100
Medical treatment using local anaesthesia	£750	£100
Hospice	£0	£0
Dental treatment under general anaesthesia	£750	£100
Cosmetic Surgery	£2,500	£100

Independent Hospital whose main purpose is providing treatment using a Prescribed Technique or Prescribed Technology¹

Category	Application fee for registration as a Provider	Application fee for registration as a Manager
In Vitro Fertilisation (IVF)	£750	£100
Class 3B or class 4 Laser products used for a non-surgical purpose	£500	£100
Class 3B or class 4 Laser products used for a surgical purpose	£750	£100
Intense Light	£500	£100
Dialysis	£750	£100
Endoscopy	£750	£100
Hyperbaric Oxygen Therapy	£750	£100
Male Circumcision	£500	£100

Other

Category	Application fee for registration as a Provider	Application fee for registration as a Manager
Independent Clinic	£500	£100
Independent Medical Agency	£500	£100

¹ As stated within the Independent Health Care (Fees) (Wales) Regulations 2011.

Stage 3: Assessment

Section 1 – How we assess your application

A. The assessment process

Section 2 - Financial assessment

B. Financial reference

C. Question on administration and receivership

D. Declaration about financial viability

Section 3 - Medical assessment

E. Medical reference

Section 4 - Professional assessment

F. Regulatory requirements

G. Personal / Professional references

H. Registered Managers 'fitness to practice' interviews

Stage 3 Section 1 – How we assess your application

A. The assessment process

There are 3 stages to our assessment process and we aim to complete all registrations within 12 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 Guide
- 2 personal / professional references for the registered manager
- Financial reference for the organisation (if applicable)
- Policies and procedures index
- Confirmation that an enhanced DBS check has been carried out or is in the process of being carried out
- 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 are missing we will contact you and 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.

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

- The quality of the information provided.
- The outcome of the 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 either:

- a) contact you to request missing information;
- b) raise queries about the information provided. If you fail to provide the required additional information within 12 weeks of the original submission of your application, HIW may refuse to grant your application; or
- c) advise you that your application has been accepted and arrange the pre-registration site visit and interview.

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

The ***second stage*** of assessment consists of our pre-registration site visit and registered manager 'fitness to practice' interview.

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

B. Financial reference

Regulation 29 of the Independent Health Care (Wales) Regulations 2011 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 business before and during the start up process as well as on a continuous basis. This is to ensure that service users will have continuity of care and treatment should we register your service.

We therefore request that you provide a financial reference which has been signed by either your bank representative or accountant. You may need to explain to your bank that we need a reference only and **not a full credit check**. A form for the reference is available at www.hiw.org.uk. If this is not received with your application we will reject your application.

C. Question on administration and receivership

The information you provide for this question will be judged with the supporting evidence on your ability to carry out or manage a service. You will be given the opportunity to discuss the details fully if needed.

D. 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. This should be a robust and comprehensive analysis of all costs you are going to face and be very realistic about your likely income. Your business plan will need to show that your income will exceed your costs within a reasonable timeframe, and that you have the finance to enable you to meet the essential standards. You should not declare your financial viability unless you have followed this process. Therefore if you answer 'no' to this question we may make a proposal to refuse your application.

Stage 3 Section 3 – Medical Assessment

You must declare if you have any physical and mental health conditions which may affect your ability to carry on, manage, or work for the purposes of the service. 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 10 of the Independent Health Care (Wales) Regulations 2011).

E. Medical reference

You also need to submit a medical reference which has been signed by your general practitioner (GP) (a form can be found at www.hiw.org.uk). If this is not received with your application we will reject your application. Please note that your GP may charge for this reference.

If the information provided in your application form or on the medical reference 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 fit 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

F. Regulatory Requirements

Regulation 12 of the Independent Health Care (Wales) Regulations 2011 outlines the requirements relating to registered managers' 'fitness to practice'.

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 establishment or agency’.** We assess this through interview, references and the application forms 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 establishment or agency’.** We assess this through the information provided in your application form, interview and through references, in particular your medical reference.

G. Personal / Professional References

You need to submit two personal/professional references with your application (a form can be found at www.hiw.org.uk). The referees must be able to comment on your competence to manage the service and should not be related to you. One of these referees should have been your employer for at least 3 months. We may contact your personal/professional referee if we have any concerns about your application. For example, a quick succession of different jobs, or an unexplained gap in employment.

H. Registered Managers ‘fitness to practice’ interview

We usually conduct ‘fitness to practice’ interviews on the same day as our site visit or invite you to attend our offices in Merthyr Tydfil.

Prior to the interview we will send you a questionnaire to fill in, which asks about the Regulations and your responsibilities as a registered manager. We ask you to return this to us prior to your interview so we can address any points relating to the regulations during the interview.

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

Section 1 – Timescales

A. When you can expect an outcome

Section 2 – Receiving a decision

B. Notice of Proposal (NoP)

C. Notice of Decision (NoD)

D. Appeals

A. When you can expect an outcome

We aim to make a decision on all new providers within 12 weeks of accepting a fully completed application to the date that the Notice of Decision is served.

Please note that the 12 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.

Stage 4 Section 1 – Timescales

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 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

B. Notice of Proposal (NoP)

When all stages of assessment have been completed, we will issue you with a Notice of Proposal (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 Notice of Decision (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/IPL services will state the specific lasers and treatments you are permitted to carry out.

C. Notice of Decision (NoD)

When the NoP has elapsed (after 28 days) or you have signed, dated and returned a slip to 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 and can start providing your service.

D. 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

- A. Certificates
- B. Website and logo
- C. Inspections

Section 2 - Your responsibilities when registered

- D. Keeping your service compliant with the Regulations
- E. Informing us of changes
- F. Reportable incidents
- G. Annual Fees
- H. Registered Manager responsibilities
- I. Providing a service when not registered.

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

A. 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 establishment.

B. Website and Logo

When you are registered with us, we will add details of your service to our website and social media accounts. 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.

C. 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

D. Keeping your service compliant with the Regulations

You are responsible for ensuring that your service 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.

E. Informing us of changes

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

If you wish to vary or remove a condition of registration you will need to submit an application to HIW and a fee is payable. Table 2 below sets out these fees. On receipt of an application HIW will confirm the fee and include information on how to make payment.

Minor variation

A minor variation is a variation of conditions where it is not necessary for HIW to inspect the establishment or agency 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:

- Reduction in bed numbers.
- Cessation of a type of treatment or service.
- Minor alterations to accommodation.
- A new Class 3B/4 laser or intense pulse light (IPL) machine 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 establishment or agency 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.

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.

Table 2 - Costs to Vary or Remove Conditions of Registration

Vary a condition of registration by a provider of any establishment or agency (except hospices)

Type of variation	Fee
Minor	£250
Major	£500

Remove a condition of registration

Category	Fee
Registered providers of all establishments and agencies (except hospices)	£50

F. Reportable incidents

Regulations 30 - 35 of the Independent Health Care (Wales) Regulations 2011 state that you must inform HIW if any of the following events occur:

- Death of a patient;
- Unauthorised absence of a patient who is detained or liable to be detained under the Mental Health Act 1983;
- Serious injury to a patient;
- Outbreak of any infectious disease;
- Allegation of misconduct against a member of staff;
- Application made to a court in relation to depriving a patient of their liberty;
- Appointment of a manager
- Notification of offences
- When a registered person, be it an individual provider or a manager, proposes to be absent from the establishment for more than 28 days consecutively;
- Notice of changes
- Appointment of liquidators
- Death of a registered person

Notifiable events guidance and forms are available at www.hiw.org.uk

G. Annual Fees

Registered providers of establishments (excluding hospices) and agencies have to pay an annual fee. Managers do not have to pay an annual fee.

You will **not** have to pay a fee:

- If you are a provider of a Hospice.
- If you are the provider of an establishment or agency and you are a charity **and** the only services provided by that charity are free **and** the charity's services are not commissioned by the NHS or a local authority.

Your annual fee is due on the anniversary of your registration and table 3 below sets out the fees that must be paid annually to remain registered with HIW.

If you are newly registered your first annual fee is payable one month after the date of your registration and thereafter on the anniversary of the date of your registration [see the date on your registration certificate].

HIW will write to advise you that your annual fee is due. Shortly after an invoice will be issued with 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 8 which states that:

- The refund will be no more than 50% of the annual fee.
- Any refund will be calculated by how many complete quarters remain of the registration year (calculated from 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.

If you have registered more than once because you operate services through separate legal entities, each of your registrations is liable for an annual fee.

Table 3 – Annual Fees**Independent Hospitals**

Category	Flat rate fee	Additional fee payable for each approved place²: 1-25	Additional fee payable for each approved place: 26-59	Additional fee payable for each approved place: 60-99	Additional fee payable for each approved place: 100+
Non-acute hospital	£1,500	£200	£100	£100	£100
Acute Hospital	£2,000	£200	£100	£50	£25
Mental Health Hospital	£2,000	£200	£100	£50	£25
Termination of Pregnancy Hospital	£1,500				
Maternity Hospital	£2,000	£200	£100	£100	£100
Hospital providing treatment using local anaesthesia	£750				
Hospice	£0	£0	£0	£0	£0
Dental treatment under general anaesthesia	£1,500				
Cosmetic Surgery	£2,000	£200	£50	£50	£50

For example if you are an Acute Hospital with 55 approved places the calculation would be:

Flat rate fee = £2,000
 Places 1-25 = 25 x £200 = £5,000
 Places 26-55 = 30 x £100 = £3,000
 Total annual fee = £10,000

² An approved place is a bed which is available at the establishment for a service user at night.

Independent Hospital whose main purpose is providing treatment using a Prescribed Technique or Prescribed Technology³

Category	Flat rate fee
In Vitro Fertilisation (IVF)	£1,500
Class 3B or class 4 Laser products used for a non-surgical purpose	£500
Class 3B or class 4 Laser products used for a surgical purpose	£750
Intense Light	£500
Dialysis	£1,500
Endoscopy	£1,500
Hyperbaric Oxygen Therapy	£1,500
Male Circumcision	£500

Other

Category	Flat rate fee
Independent Clinic	£500
Independent Medical Agency	£500

H. 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.

I. Providing a service when not registered

Any person who carries on or manages an establishment or agency which provides a relevant independent healthcare 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.

³ As prescribed in regulation 3 of the Independent Health Care (Wales) Regulations 2011.

Appendix A: Application Checklist

There is only one application form to complete if you are registering for the first time with Healthcare Inspectorate Wales.

The checklist below is the documentation required in addition to your completed and signed application form.

For all applications submitted to HIW
<ul style="list-style-type: none">• Statement of Purpose
<ul style="list-style-type: none">• Patient Guide
<ul style="list-style-type: none">• Financial reference for the organisation
<ul style="list-style-type: none">• Policies and procedures index

In addition to the above, registered managers must also provide
<ul style="list-style-type: none">• 2 personal / professional references
<ul style="list-style-type: none">• Medical reference
<ul style="list-style-type: none">• A completed DBS application form (with supporting documents) or a disclosure certificate for the update service, plus the relevant fee

In addition to the above, IPL / Laser applications must also include the following additional information
<ul style="list-style-type: none">• Evidence that you have employed a Laser Protection Advisor
<ul style="list-style-type: none">• Local Rules for each machine, signed by all users of the machine
<ul style="list-style-type: none">• Signed treatment protocols drawn up by a practicing GMC registered professional
<ul style="list-style-type: none">• Appropriate consent from the Local Authority to use laser / IPL products on the premises