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Independent Healthcare (IHC) Registration Guidance for Applicants

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You, registration and the law

Each application for registration will be considered individually, on its own merits, and in proportion to the nature, scope and size of the independent healthcare service to be provided. This may result in Healthcare Improvement Scotland requesting additional supporting documents following the submission of an application.

The questions we ask in the registration form are required by the *National Health Service (Scotland) Act 1978* and any associated regulations. The information you provide helps us decide whether your application to register an independent healthcare service should be granted.

If you are a non-healthcare professional that is applying to register an independent healthcare service, consideration should be given to fulfil the staffing regulations listed in *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*.

- A provider must, having regard to the size and nature of the service, and the number and needs of service users:
 - ensure that at all times suitably qualified and competent persons are working in the independent healthcare service in such numbers as are appropriate for the health, welfare and safety of service users, and
 - ensure that at all times a suitably qualified healthcare professional is working within the independent healthcare service while service users are present.

WARNING: It is a criminal offence to knowingly make a statement in your application which is false or misleading in a material respect. We may also refuse your application to register if you fail to provide true and accurate information.

Please note:

1. An application for registration is **only** considered complete if:

- you have completed all the relevant parts of your application form and submitted it
- you have submitted all relevant supporting documentation
- you have submitted all relevant policies and procedures, and
- you have paid the registration fee.

It will take us a **minimum of 6 months** to process **a complete application**.

Some applications can take longer than others to process. This is dependent on the complexity of the independent healthcare service to be provided.

- **No payment should be made until a registration fee request has been made by HIS.**
 - **Early payment of the registration fee does not mean that your application will be processed faster.**
 - **The registration fee is non-refundable.**
 - **Incomplete applications will be refused.**
2. Applicants should carefully consider who is providing the service. Changes to the provider of the service after the service is fully registered will result in a requirement for the new provider to register the service with Healthcare Improvement Scotland. This will mean that payment of a registration fee is required when a new application for registration is submitted.

NOTE: The duty for registering an independent healthcare service rests with the individual who intends to provide that service. That individual may be either a natural person or a body corporate. A limited company is considered a separate legal entity from any natural person, even if that person is a director of the company. Any change from a natural person providing a service to a body corporate is considered a change of individual for the purpose of registration.

Legislation, standards and best practice

Legislation

The National Health Service (Scotland) Act 1978 enables Healthcare Improvement Scotland to regulate independent healthcare services in Scotland. Healthcare Improvement Scotland took over these regulatory responsibilities from the Care Commission on 1 April 2011.

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011 are made under the above Act. You **must** demonstrate compliance with these regulations for us to approve your application to register an independent healthcare service. Providers have a duty to continue to meet the requirements of the regulations while their service is registered, and we will check compliance as part of our routine regulatory duties (for example during inspection). We have a range of formal and informal enforcement processes where the requirements for the regulations are not met. Please see our [Provider Handbook](#) for more information about our regulatory processes.

Standards

The Scottish Government's *Health and Social Care Standards: My support, my life (June 2017)* set out what people should expect when using health, social care or social work services in Scotland. These replaced the previous National Care Standards. The Standards can be found [here](#).

Best Practice

Scottish Health Planning Notes (SHPNs) and Department of Health's Health Building Notes (HBNs) where there are **no** equivalent SHPNs, should be read along with the relevant parts of the Scottish Health Technical Memorandum (SHTM) series. Where equivalent Scottish and English versions of guidance are published, Scottish guidance takes precedence. Although these documents are written for NHS health facilities, the guidance is relevant to all healthcare settings. The guiding principles should be considered in the context of each circumstance and along with relevant legislation and standards.

Which forms should I complete?

You must complete the application form as either an:

- applicant who is an individual, or
- applicant that is not an individual.

Applicant who is an individual

If you are a self-employed person working as a sole trader, then you must complete the following parts of the application form.

Part 1: Individual application

Part 1a: Individual application - Employment history

If you are completing Part 1, you will be directed to this form to record your employment history. Please create a form for each job you have held for the last 15 years. You can create as many of these sections of the form as you need.

Part 3: Appointment of a manager

You do not need to complete this part of the form if you are intending to provide and manage the service yourself.

However, if you intend to appoint a different person to manage your service, you should complete this part of the form. Registration will not be granted until a manager has been appointed. If you have yet to appoint a manager, please complete this section at a later date.

Part 3a: Manager - Employment history

You do not need to complete this part of the form if you are intending to provide and manage the service yourself.

However, if you intend to appoint a different person to manage your service, please create a form for each job the service manager has held for the last 15 years. You can create as many of these sections of the form as you need.

Part 4: Details of the proposed service

Every applicant must complete this part of the form.

Part 5: Quality of the service

Every applicant must complete this final part of the form.

Applicant who is not an individual

If you are an applicant that is not an individual, and you are either a:

- company
- association
- partnership
- limited liability partnership
- committee
- corporate body
- unincorporated body, or
- registered charity

then you must complete the following parts of the application form.

Part 2: Applicant who is not an individual

Part 2a: Applicant who is not an individual - Relevant person

You must complete a separate Part 2a application form for each relevant individual of the provider organisation:

- if you are a limited company registered with Companies House, these should match the 'people' listed on Companies House.
- if you are a charity, you should complete a separate Part 2a for each of the charity trustees.
- if you are in a partnership or limited liability partnership, committee, corporate body or unincorporated body, then you must tell us all of the people that are involved.

Part 3: Appointment of a manager

You must tell us who the manager of the service is that you are applying to register. Registration will not be granted until a manager has been appointed. If you have yet to appoint a manager, please complete this section later.

Part 3a: Manager - Employment history

If you are completing Part 3, you must complete Part 3a of the application form. Please create a form for each job the service manager has held for the last 15 years. You can create as many of these sections of the form as you need.

Part 4: Details of the proposed service

Every applicant must complete this part of the form.

Part 5: Quality of the service

Every applicant must complete this final part of the form.

Background checks

Healthcare Improvement Scotland will carry out a Disclosure Scotland background check on those intending to provide and manage an independent healthcare service.

If there is more than one relevant person (i.e. you have submitted multiple Part 2a application parts), you will need to nominate one relevant person as your key relevant person. We will undertake background checks on this key relevant person.

Disclosure Scotland can provide us with details of an individual's criminal convictions, or confirmation that they have none. The information provided by Disclosure Scotland could include:

- information about a person's inclusion on children's or adults' barred lists
- details of criminal records, or
- other relevant information held by a local police force or Government body.

We will invoice you for the cost of these checks as part of your application for registration with us. Please note that this cost is in addition to the fee to register an independent service with Healthcare Improvement Scotland.

Further information about the background checks we complete, and the costs involved can be found on our [website](#).

Data protection statement

As the independent regulator of independent healthcare services across Scotland, we have powers under the *National Health Service (Scotland) Act 1978* to collect and process personal information about people who provide, manage and work for independent healthcare services. This can include their name, address and other contact details, date of birth, qualifications, training and experience, data relevant to disclosure and Protecting Vulnerable Groups (PVG) checks, employment history including any disciplinary action and outcome.

When exercising these and other powers we are required to comply with all aspects of *The General Data Protection Regulation (GDPR) (EU) 2016/679* and *Data Protection Act 2018*. Further information can be found in our Privacy Notice available on our [website](#).

Your independent healthcare service and the Health and Social Care Standards

Our inspection methodology has been revised in line with the Scottish Government's *Health and Social Care Standards: My support, my life* (June 2017) and Healthcare Improvement Scotland's Quality Framework.

A link to the Health and Social Care Standards: My support, my life (June 2017) can be found below:

<http://www.newcarestandards.scot/>

A link to the Quality Framework can be found below:

[Healthcare Improvement Scotland quality framework – Healthcare Improvement Scotland](#)

A link to our inspection methodology can be found below:

[Independent healthcare regulation – inspection methodology – Healthcare Improvement Scotland](#)

Supporting documentation, policies and procedures

Appendices 1 and 2 detail all the supporting documents, policies and procedures that you must submit in support of your application for registration.

Your policies and procedures should be uploaded as separate documents to support your application for registration. To do this, please use the 'documents' section in the eForms portal. Please use a similar file name as indicated in the supporting documents, policies and procedures sections within this guidance to reference your documents, for example: ABC Aesthetics - Consent policy, ABC Aesthetics - Business plan).

Each application for registration will be considered individually, on its own merits, and in proportion to the nature, scope and size of the independent healthcare service to be provided. This may result in us requesting additional supporting documentation following the submission of your application.

A policy template is available on our website for you to use and adapt. [Independent healthcare regulation – policy template – Healthcare Improvement Scotland](#).

The application form

Part 1 - Individual application

If you are an individual (that is, a self-employed individual working as a sole trader) applying to register your own independent healthcare service, you should complete this part of the form.

1. Your details

We will use this information as your contact details and also to identify you as the registered provider on the Certificate of Registration.

2. Owner of the service

This is where you declare your ownership of the independent healthcare service. If you are not the owner of the service, please provide the name and full contact details of the owner.

Please consider carefully if you are completing the correct part of the form if the owner is someone other than you.

3. Manager's details

There must be a recognised appointed manager of the service. In this section, you must state if you will manage the service yourself or if you will appoint another person to manage the service for you.

If you will be the manager of the service, you must complete Section 4 - Medical declaration (below). We may send this to your own doctor to ask for a confidential statement about your physical and mental fitness to run and manage an independent healthcare service.

If you are appointing another person to manage the service on your behalf, you must complete Part 3 - Manager. If you have not yet appointed a manager, you can complete Part 3 at a later stage. It is the independent healthcare service provider's responsibility to ensure the manager meets the criteria set out in the National Health Service (Scotland) Act 1978 and any associated regulations.

4. Medical declaration

You must make this declaration if you will also be managing the service.

When considering your application, we may need to ask your own doctor for a confidential statement about your general health, noting in particular any physical or mental health issues which may affect your ability to run and manage an independent healthcare service. If we decide to seek relevant information about your health from your doctor, we will contact you again and ask you to sign and return a consent form. You will be asked to provide the contact details of your doctor at this time.

Your doctor or surgery may charge a fee for providing a statement about your health. You will be responsible for paying any fee if there is a charge for this service.

5. Employment history

Please tell us about your previous employment and self-employment for the last 15 years, using Part 1a of the application form. Please explain clearly if you have any gaps in your employment history and state what you were doing at that time. Please upload this as a separate document with employment history referenced in the file name. You must also explain clearly if you were dismissed from any previous employment, using the reason for leaving box.

6. Technical and professional qualifications

Please tell us about any technical and/or professional qualifications you have. Please also tell us if you are registered with a professional or regulatory body. Please ensure that you include full registration details including the name of the regulatory body, your registration or PIN number, and when your registration is due to expire and/or is due to be renewed. If you have more than three relevant qualifications, please detail these in a separate document and upload it with 'tech and prof qual' referenced in the file name.

7. References

Please provide us with the names and full contact details (postal addresses including postcodes, email addresses and telephone numbers) of two people who are able to provide references about your good character and competence to provide an independent healthcare service of the kind you are proposing.

Your referees must:

- **not** be a relative
- be your employer, where you have been employed by one employer for at least 3 months in the last 15 years.

8. Invoice contact details

Please provide us with the full contact details for the person who we should invoice for the Healthcare Improvement Scotland annual continuation fees. We will require the person's full name, designation and full postal address including postcode.

9. Financial information

The ongoing support and care for service users is very important. Therefore, we need to understand how you will make provision for the continued support of your service users in the event that your service ceases trading. Please tell us about the arrangements you have put in place to address this.

10. Declaration about bankruptcy and sequestration

If possible, please make the declaration in respect of bankruptcy and sequestration. If you are unable to make the declaration, you have the opportunity to explain why. Please answer the additional questions and provide full details in the space provided. We will take account of the explanations and details when considering your application.

11. Declaration about convictions and prosecutions

The *Rehabilitation of Offenders Act 1974 (Exclusions and Exemptions) (Scotland) Order 2003* requires that anyone applying to register an independent healthcare service must declare all convictions whether 'spent' or not. Any failure to disclose convictions may result in refusal of your application. All information you give us will be kept confidential.

The disclosure of conviction(s) does not necessarily exclude an applicant from becoming registered to provide an independent healthcare service. We will take into account the nature of the offence(s) when considering your application. In addition to the information you provide here, we will carry out background checks on you, including criminal record checks.

12. Declaration about your previous involvement in registered services

Please provide us with any information about your involvement in other registered healthcare or social care services.

Part 2 - Applicant who is not an individual

Any applicant who is not an individual must complete Part 2 of the application form. An applicant who is not an individual is an organisation. This means companies, associations, charities, partnerships, limited liability partnerships, committees and all corporate and unincorporated bodies. It is important that the legal status of the independent healthcare service is confirmed.

In Part 2, where we ask for details of the applicant, we mean the applicant organisation. Do not give details of the person completing the form or any other person involved in the management or control of the applicant organisation, unless we specifically ask for such information.

1. Applications by companies

Please tell us about any of the applicant's subsidiary or associated companies. An associated company, for example a parent or holding company, is where one company has control of another or both companies are under the control of the same person.

Please confirm the financial relationship between the subsidiary company and the independent healthcare service applying to be registered.

Part 2a

1. Details and declarations of directors, managers, company secretary, partners, office bearers

Please use Section 1 of Part 2a of the application forms to list the full name, date of birth, address (including postcode) and telephone number of every person who is, or acts as:

- a director, manager or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

You can create as many Part 2a forms as you need. You can do this by clicking 'add new application to register' on the top right-hand side of the screen when you are logged into the portal.

If your organisation is registered with Companies House, you should complete a new Part 2a for each 'person' listed on Companies House. All persons listed on Companies House must complete a Part 2a regardless of how active they are within your organisation.

2. Services that members of the organisation have previously provided

This declaration must be made by every person who is, or acts as:

- a director, manager or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

3. Bankruptcy and sequestration

This declaration must be made by every person who is, or acts as:

- a director, manager or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

If you are unable to make the declaration, you have the opportunity to explain why. We will take account of the explanations and details when considering your application.

4. Declarations about convictions and prosecutions

This declaration must be made by every person who is, or acts as:

- a director, manager or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

Regulation 5 of the Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011 states that a person shall not provide or manage a healthcare service, unless the person is fit to do so.

When we consider applications made by non-individual applicants, we must consider whether the officers and individuals concerned in the management and control of the applicant organisation are of integrity and good character.

'Relevant individuals' are persons who act as:

- a director, manager or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

If the organisation has more than one relevant individual, you will need to nominate one relevant individual as the key relevant individual. We will complete Disclosure Scotland background checks on the key relevant individual.

Please note that it is an offence to give false information as part of an application to register an independent healthcare service. Failure to provide true and accurate information may result in refusal of the application to register a proposed independent healthcare service with Healthcare Improvement Scotland.

The Rehabilitation of Offenders Act 1974 (Exclusions and Exemptions) (Scotland) Order 2003 requires that anyone applying to register an independent healthcare service must declare all convictions whether 'spent' or not. Any failure to disclose convictions may result in refusal of the application to register the proposed independent healthcare service with Healthcare Improvement Scotland. Any information provided will be confidential. The disclosure of conviction(s) in relation to a relevant individual does not necessarily exclude an applicant from becoming registered. Full consideration will be given and the nature of the offence(s) will be taken into account.

Please note that independent healthcare providers must give written notice to Healthcare Improvement Scotland without delay, as soon as it is practicable to do so, to inform us if there is any change in the ownership of a corporate body or the identity of its officers while an application for registration is in progress. For example, the resignation of the company secretary or director; or where there is any change in the partnership of a firm, for example new partners joining and/or existing partners leaving. Healthcare Improvement Scotland may request background checks and reference questionnaires for these individuals.

5. References

Please provide the full names and contact details of two people who can give a reference about their integrity, good character and ability in providing an independent healthcare service, for each person who is, or acts as:

- a director, manager or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

Referees must:

- **not** be a relative
- be your employer, where you have been employed by one employer for at least 3 months in the last 15 years.

6. Statement about the applicant's previous involvement in registered services

This question is about the applicant (the organisation which is applying to register). The person who is completing this form should complete this question on behalf of the applicant.

7. Manager's details

If you are an individual and you intend to appoint a manager to the service, you must complete Part 3 - Appointment of a manager.

If you are an applicant who is not an individual, you must complete Part 3 - Appointment of a manager.

If you have not yet appointed a manager, you can complete Part 3 at a later stage. It is the independent healthcare service provider's responsibility that the manager meets the criteria under the National Health Service (Scotland) Act 1978 and any associated regulations and other legislation.

8. Business plan and accounts

For inpatient services only:

To assess the business planning and financial viability of the applicant organisation, please provide:

- evidence of the existence of a business bank account. (Should one not exist, you should contact your bank to establish a business bank account independent of any domestic accounts) - **new and existing businesses**.
- financial forecast - **new and existing businesses**.
- copies of annual accounts for the last 3 financial years. (If no accounts exist, you should provide copies of tax returns to HMRC covering the same period) - **existing businesses only**.
- business plan - **new businesses only**.

9. Financial information

For inpatient services only:

To consider the application, please provide us with **a statement from your bank** about the applicant organisations or partnership's financial standing and reliability, in respect of the operation of the proposed independent healthcare service. Your bank may charge a fee for providing such a statement. You will be responsible for paying any fee if your bank charges for this service.

The ongoing support and care for service users is very important. Therefore, we need to understand how you will make provision for the continued support of your service users in the event that your service ceases trading. Please tell us about the arrangements you have put in place to address this

10. Character and integrity of the applicant

We must consider whether the applicant organisation or partnership is of good character and integrity. To assess this, please tell us about any prosecutions, convictions, actions for negligence, reparation claims, actions in relation to health and safety and employment tribunals relating to the applicant organisation.

Part 3 and 3a - Appointment of a manager

Only complete Part 3 and 3a of the application form if:

- you are an applicant who is an individual and you intend to appoint a manager for the service.
- you are an applicant who is not an individual.

If you have not recruited a manager yet, you can complete this part of the application form later. However, we will not progress your application for registration until the manager has been appointed.

1. Employment history

Please tell us about the manager's previous employment and self-employment for the last 15 years, using Part 3a of the application form. Please explain clearly if you have any gaps in your employment history and state what you were doing at that time. Please upload this as a separate document with manager employment history referenced in the file name. You must also explain clearly if they were dismissed from any previous employment, using the reason for leaving box.

2. Medical declaration

This declaration must be completed by the proposed manager.

3. References

Your referees must:

- **not** be a relative
- be your employer, where you have been employed by one employer for at least 3 months in the last 15 years.

4. Declaration about care services the proposed manager has provided before

This declaration must be completed by the proposed manager.

5. Declaration on behalf of the applicant

It is an offence for a person who is not fit to act as a manager in an independent healthcare service to do so in terms of Regulation 5 of *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*.

Part 4 - Details of the proposed service

1. Proposed service

Please provide the details of the proposed service.

2. Times of operation

Please set out clearly when your service operates. This should include daily opening times, schedules for opening if you do not open every day of the week and set out any regular periods of extended closure.

3. Beginning the service

Please state the date you propose to start operating the service. The actual date that the service commences will be confirmed as a part of the registration process.

Please note that it is an offence to operate an independent healthcare service before registration has been granted. This also includes the period that Healthcare Improvement Scotland takes to process your application for registration.

Services are not permitted to trade until registration is granted by Healthcare Improvement Scotland.

If you are currently providing an NHS dental service, you should plan to retain your NHS list number until your registration with Healthcare Improvement Scotland is completed. This will allow you to provide continuity of care to your patients.

4. Statement of aims and objectives

Please provide a statement of the aims and objectives of the proposed independent healthcare service. You can attach your aims and objectives statement document at the end if you prefer.

5. Information about service users

Please tell us:

- the age range and gender of service users
- the maximum number of service users, and
- any criteria you will use to select service users, other than age or gender - such as the referral criteria or who the care service proposes to offer care and treatment to.

6. Staffing

Please tell us how the service will be staffed, based on the numbers of people using the service and their needs. Tell us what staff groups you will have (including management, care and ancillary), what posts you propose to have and what qualifications you will require staff to have. Please also include details of other practitioners that will be working under practising privileges.

7. People who will be employed in the service

Tell us how many people will be employed by the service.

8. Numbers and needs of people using the service and staffing provision

Please tell us about the employee-to-service user ratio (how you will work out the number of staff required to meet the needs of the people using the service), excluding ancillary staff and supervisory managers. Please describe how you will manage and allocate staff resources based on service user need, service activity and healthcare risk. For example, patients under constant observation, pre- and post-theatre days and observation within high dependency unit (HDU).

9. Recruitment policy

Please tell us the proposed independent healthcare service's policy on recruitment, interviewing, selection and checking of references and other documentation for all those who will work in the proposed independent healthcare service, including volunteers.

10. Staff training

Please tell us your proposals for staff induction and ongoing training and development.

11. Infection prevention and control

Please detail what arrangements are in place for infection prevention and control.

12. Equipment and services

Describe the services that will be provided, including the nature of treatments, such as no physical contact, topical, injection, laser or Intense Pulse Light treatments, chemical deep skin treatments, treatments under local anaesthetic treatments under sedation and treatments under general anaesthetic.

Describe the equipment used, including the type of clinical equipment and facilities, such as operating theatres, treatment rooms and consulting rooms that will be used.

Detail any arrangements for the supply of blood and blood products and for the provision of pathology or radiology services.

Detail any services which are to be provided to children.

Where the proposed service is an independent hospital, detail any arrangements for the attendance at all times of a registered medical practitioner.

Describe medicines management and accountable officer arrangements, for example pharmacy on/off site who will be providing pharmacy advice.

Describe, if applicable, arrangements to access external laser and radiology protection advisers and internal supervisors, etc.

13. Insurance details

Please provide copies of:

- indemnity insurance
- public liability insurance, and
- employer's liability insurance (if applicable).

If you do not have insurance in place yet, please provide copies of the insurance proposals you have.

14. Description of premises

Regulation 10 of *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*, states that 'a provider must not use premises for the provision of an independent healthcare service unless they are fit to be so used'.

If you rent the premises from a property landlord or owner, please submit a copy of your lease agreement with this application. If you provide the independent healthcare service from premises which you do not own and do not have a lease agreement, or in domestic premises, for example your own home, or someone else's home, please consider carefully if you are able to demonstrate clearly that the premises are fit to be used for the provision of an independent healthcare service.

Any premises used to provide an independent healthcare service need to be safe, clean and suitable for seeing and treating service users, for members of staff who work there, and for any visitors to the service.

15. Suitability of accommodation and premises

We will ask you to confirm that the premises are presently capable of being used for the purposes of achieving the aims and objectives of the independent healthcare service.

If they are not, please provide the following details:

- planning permission
- building works or conversion required
- completion certificate in relation to new builds or substantial building works.

16. Fitness of premises

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011, are made under this Act and require the following in terms of premises:

- 'Regulation 10(1) states that 'a provider must not use premises for the provision of an independent health care service unless they are fit to be so used'.
- Regulation 10(2) states that 'a premises are unfit to be used for the provision of an independent health care service unless –
(a) they are suitable for the purpose of the independent healthcare service'; (b) they are of sound construction and kept in a good state of repair both externally and internally; and
(c) they have adequate and suitable equipment, ventilation, heating and lighting.'
- Regulation 3(a) states that a service provider must 'make proper provision for the health, welfare and safety of service users'.
- Regulation 3(d)(i) states that a service provider must 'have appropriate systems, processes and procedures for all aspects of care and treatment carried out by the independent health care service including in particular – the prevention and control of infection'.

Your premises must be 'suitable for the intended purpose' and meet all construction, repair and maintenance statutory requirements.

Please tell us what arrangements you have in place to ensure the safe maintenance and correct operation of any gas, electrical and fire safety equipment.

Please tell us what arrangements you have in place for the maintenance and correct operation of any clinical equipment, such as laser equipment.

Please tell us who owns the premises. If rented, please tell us the full name of the landlord.

In order to determine if the premises are 'fit to be so used', you can either follow recognised published guidance for the construction of healthcare premises, or if you consider that the potential hazards in your service are not significant enough to warrant the application of such guidance, then you must undertake a risk assessment to demonstrate how you will mitigate and control any hazards created by the gap between the recognised standard and the alternative you intend to use. Any risk assessment should be undertaken by a person that is competent to do so, for example risk assessments relating to electricity and electrical safety should be carried out by an electrician or someone similarly competent.

Risk assessment is a recognised and formal way of identifying hazards, evaluating risk and identifying controls and mitigation to minimise that risk.

The risk assessment should clearly set out the intention of the process and identify the gap between the recognised standard set out in appropriate guidance and the standard you consider to be appropriate for your service. The document should then set out the hazards associated with this alternative standard, the impact should it come to pass, the likelihood it may happen alongside the controls and mitigation to reduce the inherent risk. It should detail how you intend to control any potential risk or adapt the workplace to mitigate any risks identified. You will need to consider how you will monitor the performance of any control measures.

Public Health Scotland have helpful guidance on how to complete a risk assessment on their [Healthy Working Lives](#) website.

Although the requirement in health and safety law is for risk assessments to be documented where you have 5 or more employees, in this case as we are looking at the process to support an explanation as to why you are not meeting recognised healthcare guidance and therefore, we expect that these will be written up in a recognisable risk assessment format. The key elements that a risk assessment requires are:

- consideration of who is potentially at risk and the way in which they may be harmed or injured
- demonstration of any steps you have taken immediately to control the risk; and
- whether this is adequate to mitigate the risk or what further action you plan to take.

It is important to note any responsible individuals and their roles and any associated dates for changes to be in place. It is also important to ensure risk assessments are reviewed regularly and therefore an assessment date and review date should be clear within the document.

Healthy Working lives also provide guidance on [how to document a risk assessment](#).

There must be a designated clinical area (treatment room/s) where treatments will be provided from.

Scottish Health Planning Note 36 Part 1 – General Medical Practice Premises in Scotland provides guidance on all aspects of the design and build of a primary care facility that may be broadly similar to the requirements for an independent clinic. This may be helpful for those considering registering a small to medium size enterprise.

Please ensure your supporting policies and procedures support the statements in the regulations detailed in this section.

17. People who are not service users who live at the premises

If the independent healthcare service is to be provided in a private residence, for example your own home, or someone else's home, careful consideration needs to be given to people who live there on a permanent or temporary basis. The area of the premises designated as the healthcare environment needs to be considered in relation to its proximity to the domestic parts of the premises where other people live.

It is the responsibility of the independent healthcare service provider to ensure that no service users are seen, treated or cared for in premises where another person or persons are unfit to be in the proximity of service users.

This means that people who live in the premises, aged 16 and over, and are not involved in the provision of the healthcare service, for example immediate family members, partners, other relatives, friends or people who are lodging, may also need to have a background check carried out.

It is important that people who use an independent healthcare service in domestic premises are protected from actual or potential risks. This means that, as an independent healthcare provider, you must be able to confirm that any other persons living at the premises do not pose any risk.

A Disclosure Scotland background check must be completed for these individuals. Information about the background checks that must be completed can be found on our [website](#).

18. Declaration of individual applicant

If you are an individual applicant, please complete this declaration.

19. Declaration of an applicant who is not an individual

If you are an applicant that is not an individual, please complete this declaration.

Supporting documentation

Supporting documents	Who needs to submit this	Guidance
Annual accounts for the last 3 years (if already trading)	Inpatient services only (Existing businesses)	Independent healthcare regulation – financial guidance – Healthcare Improvement Scotland
Business plan	Inpatient services only (New businesses)	Independent healthcare regulation – financial guidance – Healthcare Improvement Scotland
Financial forecast	Inpatient services only (New and existing businesses)	Independent healthcare regulation – example financial plan – Healthcare Improvement Scotland
A statement from your bank about your financial standing	Inpatient services only (New and existing businesses)	Independent healthcare regulation – financial guidance – Healthcare Improvement Scotland
Professional indemnity insurance certificate	All applicants	N/A
Public liability insurance certificate	All applicants	N/A
Employers liability insurance certificate	Applicants that employ staff only	N/A

Proof of ownership or lease agreement for the premises	All applicants	N/A
Copy of fire risk assessment	All applicants - does not apply to mobile services with no fixed premise address	Fire safety risk assessment - Forms and records - Resources - Healthy Working Lives - Public Health Scotland
Plans of the premises	Applicants - new build premises only	N/A
Copy of planning permission	Applicants - new build premises only	N/A
Copy of building warrant	Applicants - new build premises only	N/A
Copy of building completion certificate	Applicants - new build premises only	N/A
Surveyor's report	Applicants - new build premises only	N/A
Partnership agreement	Applicants who are a partnership or limited liability partnership, committee, corporate body or an unincorporated body only	N/A

Constitution or working agreement	Applicants who are a partnership or limited liability partnership, committee, corporate body or an unincorporated body only	N/A
A copy of your Home Office License for Controlled Drugs	Applicants who produce, supply, possess, import or export controlled drugs only	N/A

Part 5 - Quality of the service

Policies and procedures

Your policies and procedures should detail how the service intends to meet the needs of individual service users and should have regard to the type of service, the size of the service, the statement of aims and objectives, and the number of service users that can be accommodated.

Supporting policies and procedures	Who needs to submit this	Guidance
Arrangements for Dealing with Emergencies including resuscitation policy	All applicants	<p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p> <p>The Resuscitation Council (UK) https://www.resus.org.uk/</p>
Consent policy	All applicants	<p>Adults with Incapacity (Scotland) Act 2000 Mental Health (Care and Treatment) (Scotland) Act 2003 http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf</p> <p>Consent Guidance – General Medical Council https://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp</p> <p>Standards - Nursing and Midwifery Council Standards - The Nursing and Midwifery Council</p> <p>Consent Guidance – General Pharmaceutical Council In practice: Guidance on consent</p> <p>Consent Guidance – General Dental Council General Dental Council - Obtain valid consent</p>

		Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot
Chaperone policy	All applicants	GMC guidance – chaperones Intimate examinations and chaperones - GMC The MDU – Guide to chaperones Guide to chaperones - The MDU

<p>Policy about protecting people from harm or abuse (adult protection/ child protection)</p>	<p>All applicants (services treating children will also require a child protection policy)</p>	<p>Adult Support and Protection (Scotland) Act 2007 http://www.legislation.gov.uk/asp/2007/10/contents</p> <p>Adults with Incapacity (Scotland) Act 2000 Mental Health (Care & Treatment) (Scotland) Act 2003</p> <p>Mental Welfare Commission https://www.mwcscot.org.uk/</p> <p>Adult Support and Protection https://www.gov.scot/policies/social-care/adult-support-and-protection/</p> <p>Child Protection https://www.gov.scot/policies/child-protection/</p> <p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p> <p>All signposted sources will have guidance about children as service users.</p>
<p>Privacy, dignity and respect of service users</p>	<p>All applicants</p>	<p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p>
<p>Medication policy</p>	<p>All applicants</p>	<p>Healthcare Improvement Scotland medicines management governance tool Independent healthcare regulation – medicines governance audit tool – Healthcare Improvement Scotland</p> <p>High Level Principles for Remote Prescribing Independent healthcare regulation – high level principles for remote prescribing – Healthcare Improvement Scotland</p>

Information management policy	All applicants	<p>Legislation - Scottish Statutory Instrument No 182 (4) http://www.legislation.gov.uk/ssi/2011/182/contents/made</p> <p>Legislation - Freedom of Information www.legislation.gov.uk/asp/2002/13/contents</p> <p>Caldicott Guardian http://www.gov.scot/Publications/2011/01/31115153/0</p> <p>Guidance - Data protection https://ico.org.uk/for-organisations/</p> <p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p>
Infection prevention and control policy	All applicants	<p>Legislation – Scottish Statutory Instrument No 182 Regulation 3(i) http://www.legislation.gov.uk/ssi/2011/182/contents/made</p> <p>Healthcare Improvement Scotland Healthcare Associated Infection Standards 2022 Infection prevention and control standards – Healthcare Improvement Scotland</p> <p>Guidance - Health Protection Scotland’s National Infection Prevention and Control Manual http://www.nipcm.scot.nhs.uk/</p> <p>Guidance - Scottish Health Technical Memorandum 64 – Clinical hand wash basins Building component series – Sanitary assemblies (SHTM 64) National Services Scotland</p> <p>Guidance - Scottish Environmental Protection Agency (SEPA) – waste Waste Scottish Environment Protection Agency (SEPA)</p>

		<p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p>
Health and safety policy	Applicants that employ 5 or more staff only	<p>Applicants that employ five or more staff must have a written health and safety policy. However, all applicants must put in place (and be able to demonstrate) their arrangements for managing health and safety risks.</p> <p>Health and Safety Executive Health and safety basics for your business</p> <p>Healthy Working Lives Healthy Working Lives - Public Health Scotland</p>
Participation policy	All applicants	<p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p> <p>Scottish Health Council Participation toolkit hisengage.scot/engaging-communities/participation-toolkit/</p>
Complaints policy	All applicants	<p>Legislation - Scottish Statutory Instrument No 182 (15) http://www.legislation.gov.uk/ssi/2011/182/contents/made</p> <p>SPSO Guidance How to handle complaints SPSO</p> <p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p> <p>Please include the following text in your policy:</p>

		<p>Healthcare Improvement Scotland is the regulator for independent healthcare services across Scotland and can accept complaints at any time from a complainant.</p> <p>Contact details are:</p> <p>Healthcare Improvement Scotland Independent Healthcare Team Gyle Square, 1 South Gyle Crescent, Edinburgh, EH12 9EB</p> <p>E: his.ihsregulation@nhs.scot</p>
Duty of candour policy	All applicants	<p>Legislation Duty of Candour - Healthcare standards - gov.scot</p> <p>Independent healthcare regulation – duty of candour template for providers – Healthcare Improvement Scotland</p> <p>How to make a good apology https://www.spsa.org.uk/sites/spsa/files/communications_material/2018%20SPSO%20Apology%20Guidance.pdf</p>
Recruitment and induction policy	Applicants that employ staff only	<p>Legislation – Scottish Statutory Instrument 182 http://www.legislation.gov.uk/ssi/2011/182/contents/made</p> <p>Protection of Vulnerable Group Guidance https://www.disclosurescotland.co.uk/publications/</p> <p>Recruitment Guidance How employers should recruit - Recruitment - Acas</p>

		<p>Safer Recruitment Through Better Recruitment https://hub.careinspectorate.com/media/1608/safer-recruitment-through-better-recruitment.pdf</p> <p>Health Clearance for Tuberculosis, Hepatitis B, Hepatitis C and HIV for New Healthcare Workers https://www.gov.scot/publications/health-clearance-tuberculosis-hepatitis-b-hepatitis-c-hiv-new-healthcare-workers-direct-clinical-contact-patient/</p> <p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p>
Staff training and development policy	Applicants that employ staff only	<p>Legislation – Scottish Statutory Instrument No 182 Regulation 12(c) http://www.legislation.gov.uk/ssi/2011/182/contents/made</p> <p>Guidance http://www.acas.org.uk/media/pdf/r/b/Starting_staff_-_induction_Nov.pdf</p> <p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p>
Practicing privileges policy and contract	Applicants that offer practicing privileges	<p>Practicing Privileges Principles https://www.healthcareimprovementscotland.scot/publications/independent-healthcare-regulation-practising-privileges-principles/</p> <p>Practising Privileges checklist for services https://www.healthcareimprovementscotland.scot/publications/independent-healthcare-regulation-practising-privileges-checklist-for-clinics/</p>

Bullying and harassment policy	Applicants that employ staff only	<p>Guidance http://www.acas.org.uk/index.aspx?articleid=797</p>
Whistleblowing policy	Applicants that employ staff only	<p>Guidance http://www.acas.org.uk/index.aspx?articleid=1919</p> <p>Raising Concerns http://www.hse.gov.uk/contact/concerns.htm</p>
Equality and diversity policy	Applicants that employ staff only	<p>Legislation – Equality Act 2000 http://www.legislation.gov.uk/ukpga/2010/15/contents</p>
Clinical governance policy	Applicants that employ staff only	<p>Health and Social Care Standards Health and Social Care Standards: my support, my life - gov.scot</p> <p>Clinical and Care Governance Framework: Guidance https://www.gov.scot/publications/clinical-care-governance-framework/pages/5/</p>
Laser safety local rules	Applicants that provide laser or IPL treatments only	<p>Legislation – Scottish Statutory Instrument No 182 (3)(v) http://www.legislation.gov.uk/ssi/2011/182/contents/made</p> <p>Guidance - Medicines and Healthcare products Regulatory Agency Guidance for safe use in medical, surgical, dental and aesthetic practices https://www.gov.uk/government/publications/guidance-on-the-safe-use-of-lasers-intense-light-source-systems-and-leds/</p> <p>Association of Laser Safety Professionals – register of Laser Protection Advisors and core of knowledge trainers Find an LPA – The Association of Laser Safety Professionals (ALSP)</p>

Radiation safety policy	Applicants that provide treatments involving ionising radiation sources only	Legislation http://www.hse.gov.uk/radiation/ionising/legalbase.htm Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) – Healthcare Improvement Scotland
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Other guidance you should consider/may find helpful

Environment	All services	List of HFS national guidance for services to consider HFS Guidance Index National Services Scotland
	All applicants	Building component series – Sanitary assemblies (SHTM 64) Building component series – Sanitary assemblies (SHTM 64) National Services Scotland

Service type

Please indicate which type of service you are applying to register:

- independent hospital
- independent clinic
- independent medical agency

Evaluating the service

The Health and Social Care Standards state that service users should be able to evaluate the services they use. Please detail how you plan to evaluate the service. Please provide a participation policy in support of your application for registration.

What happens next?

We will write to you to request payment of your registration fee once we have received your **complete** application.

An application for registration is **only** considered complete if:

- you have completed all the relevant parts of your application form and submitted it
- you have submitted all relevant supporting documentation
- you have submitted all relevant policies and procedures.

It will take us a **minimum of 3 months** to process **a complete application.**

Some applications can take longer than others to process. This is dependent on the complexity of the independent healthcare service to be provided.

You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Officer on **0141 225 6999** or email contactpublicinvolvement.his@nhs.scot



www.healthcareimprovementscotland.scot

Edinburgh Office: Gyle Square | 1 South Gyle Crescent | Edinburgh | EH12 9EB

Telephone: 0131 623 4300

Glasgow Office: Delta House | 50 West Nile Street | Glasgow | G1 2NP

Telephone: 0141 225 6999

The Healthcare Environment Inspectorate, the Scottish Health Council, the Scottish Health Technologies Group, the Scottish Intercollegiate Guidelines Network (SIGN) and Scottish Medicines Consortium are part of our organisation.

