Healthcare Improvement Scotland

Regulation of Independent Healthcare

Providing an independent clinic from fixed premises

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Contents

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 in order 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 to 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.

You, registration and the law

The questions we ask in the pre-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.

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

We will ask you to provide us with additional supporting documents as part of the application process. This will allow us to identify any gaps and suggest possible improvements to ensure the premises are suitable.

It will take us a minimum of 3 months to process a complete application from the date of payment of your registration fee. Some applications can take longer than others to process. This is dependent on the complexity of the service being proposed.

Registration fees are not refundable.

The service cannot operate until registration is approved by Healthcare Improvement Scotland.

Language used in this document

Verbs such as '**must'** and '**should'** are used throughout this document. **'Must'** is used when indicating compliance with the law. **'Should'** is used to indicate a recommendation (not mandatory), in other words, among several possibilities or methods, one is recommended as being particularly suitable - without excluding other possibilities or methods.

Introduction

This document provides guidance for providers applying to register an independent healthcare service that will operate from fixed premises. It also applies to registered providers who are applying to:

- change a service address, and/or
- change the conditions of registration (for example from non-surgical to surgical treatments).

This document **does not** cover the registration process and should be read along with our registration guidance for applicants.

Links to the relevant legislation, Health and Social Care Standards and Healthcare Improvement Scotland policies, guidance and registration information can be found on our website.

Using this guidance does not guarantee that any particular application for registration or variation will be granted. Each application will be considered individually on its own merits and in proportion to the nature, scope and size of the service proposed.

As a provider, you are responsible for complying with legal requirements of running an independent healthcare service and this document is designed to assist you with this. You also remain responsible for seeking additional advice from the relevant statutory agencies about health and safety, fire safety, planning and building control requirements. This document is designed to assist you. It is not intended to be an exhaustive guide to every aspect of developing premises for use as an independent healthcare service.

Our Provider Handbook also provides useful guidance on what you can expect going forward as a provider of a service regulated by Healthcare Improvement Scotland.

What are suitable premises?

Healthcare facilities must support the provision of high quality healthcare. Therefore, you must ensure your service premises are fit to be used for independent healthcare provision. *Table 1* highlights the specific requirements, as defined in *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*.

Table 1 (Regulation 10: Fitness of premises)

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011	
Regulation	**Requirement**
10(1)	A provider must not use premises for the provision of an independent health care service unless they are fit to be so used.
10(2)	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 health care 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.

Fitness of premises

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

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.
Risk assessment - Workplace guidance - Healthy Working Lives - Public Health Scotland

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, and
- 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; this can be found at the following link.
Risk assessment - Forms and records - Resources - Healthy Working Lives - Public Health Scotland

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.

The information contained in the rest of this document sets out the standards we expect to see are based on recognised published guidance on the built environment in healthcare setting and good practice.

Fixtures and fittings

Fixtures and fittings should be minimal, appropriate for a clinical setting and in good working order. In line with relevant guidance, as set out in Chapter 4 of Health Protection Scotland's *National Infection Prevention and Control Manual*, walls, floors, worktops, cupboards and shelves should:

- be free from damage
- be seamless and smooth
- be impervious (sealed)
- be slip resistant
- be easily cleanable
- have coving between the floor edge and wall
- be free from gaps, and
- be able to withstand cleaning and disinfection.

Coving between the floor and the wall will allow easy cleaning and prevent accumulation of dust and dirt in corners and crevices. The material used for coving should be integral with, and have similar properties to, the floor finish. All flooring should be slip-resistant. In areas where frequent wet cleaning methods take place, the flooring material should be intact and able to withstand cleaning and disinfection.

Carpets should not be used in clinical areas. Exceptions may include palliative care settings and talking only therapies. However, if there is a risk of blood/body fluid contamination in these areas, the carpets must[1] be able to withstand exposure to a disinfectant solution of 10,000 parts per million available chlorine.

Wall surfaces should be seamless and free from cracks, open joints or crevices. Solvent-free paint should be used. Walls penetrated by pipes and ducts should be sealed to prevent entry of pests, to maintain fire resistance and to make them easy to clean. Additional protection to walls should be considered to guard against impacts from mobile equipment.

Room sizes

Each treatment room should have sufficient space to work in and move around safely. The minimum recommended size of both consulting rooms and treatment rooms is 8 square metres*. Treatment rooms may be used for consultations and examinations. However, where separate consulting and treatment rooms are provided, there should not be adjoining doors between adjacent rooms for patient privacy. The waiting area should also be increased in size to accommodate these additional patients.

[1] National Infection Prevention and Control Manual: Home (scot.nhs.uk)

All rooms should have solid lockable doors to provide privacy and dignity to patients during treatment and/or consultation (privacy screens alone are not sufficient).

A clinical hand wash basin should be provided and space should be available to allow for the storage of equipment and sterile supplies.

**HBN 00-03 Designing generic clinical and clinical support spaces*

Hand washing facilities

Clinical hand wash basins and scrub-up troughs that comply with Scottish Health Technical Memorandum 64 (SHTM 64) should be provided in all patient treatment areas. They should be designated for hand washing only and not dual purpose (eg used for both hand washing and the cleaning of equipment) as this will significantly increase the risk of hand and environmental contamination. The requirements for a typical clinical hand wash basin are set out on page 9 of the memorandum and in sheet 7 on page 44 of SHTM 64.

Basins should be sufficient in number and of appropriate size to encourage and assist staff to easily conform to hand hygiene protocols. The dimensions should be large enough with curved sides to contain most splashes and enable the correct hand wash technique to be performed without excessive splashing. This can also occur if the water outlet is placed too high above the basin.

Liquid soap dispensers should be wall mounted at each basin and designed to be operated without contamination from the user's hands. Soap dispenser cartridges should be single use and not refillable. Hands-free foot operated waste bins, with appropriate colour-coded waste bags, should be provided by each basin.

Disposable paper towel dispensers should be wall mounted at each basin. The use of paper towels in rolls is discouraged as they are difficult to tear off without contaminating the remaining roll. Fabric towels are a source of cross-contamination and must not be used for hand hygiene. Hot-air hand dryers reduce paper waste and may be considered for use in public areas of healthcare facilities.

Ventilation

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 health care service unless they are fit to be so used" and that "Premises are unfit to be used for the provision of an independent health care service unless … they have adequate and suitable equipment, ventilation, heating and lighting." The ventilation requirements of each registration application will be assessed case-by-case using the provider's own risk assessment as a basis for this, if they are choosing standard of ventilation other than that set out in recognised

guidance. We no longer require a ventilation engineer report as part of the registration process.

When undertaking this risk assessment, it should be based on the providers' understanding of the service they are proposing to deliver and the requirement for the provider to ensure that they meet all relevant legislation. This includes appropriate building regulations and building standards, health and safety at work legislation and guidance, as well as legislation and guidance relevant to the provision of healthcare.

There is more information on risk assessments and how to carry them out on page 7 of this document.

All Independent Healthcare Providers must ensure that they consider wider aspects of ventilation, including the statutory requirements of Building (Scotland) Regulations 2004, and the requirement to consider Health and Safety at Work etc. Act 1974, Control of Substances Hazardous to Health Regulations (COSHH) and Workplace (Health, Safety and Welfare) Regulations. In relation to healthcare, you should still consider the guidance in Scottish Health Technical Memorandum 03-01 (Interim Version) Specialised ventilation for healthcare premises parts A and B if it is relevant to your service. It may also be helpful to consider Scottish Health Planning Note 36 – General Medical Practice Premises in Scotland, where there may be parallels between the design and use of an GP practice clinic building and a non – surgical independent clinic.

Equipment

Any fixed and portable equipment provided for use in your premises must be adequately maintained. Depending on the equipment type, these legally required checks can range from routine portable electrical appliance testing through to servicing, testing and/or calibration at pre-determined intervals. Some examples are detailed below. However, this list is not exhaustive and it is for individual providers to understand which equipment checks are required and demonstrate how these are being met.

Equipment	What's required	How often	Who by	Legislation reference
Gas boiler	Serviced and tested	Annually	Certified Gas Safe engineer	HSE Gas safety
Portable electrical appliances	Suitably maintained	At appropriate intervals (depending on level of stress on plug/wiring. More frequent testing if appliance	Competent person	HSE Maintaining portable electrical equipment

		plugged/ unplugged often)		
Fixed electrical wiring	Electrical installation condition report (EICR)	Normally minimum every 5 years	Registered electrician	HSE Introduction to electrical safety
Passenger lifts and lifting equipment (e.g. slings and hoists)	Written scheme of examination and a thorough examination	At statutory intervals (every 6 or 12 months) as per written scheme	Competent person	HSE Thorough examination and testing of lifts
Pressure systems (e.g. compressor or autoclave)	Written scheme of examination	At statutory intervals (every 12 months) as per written scheme	Competent person	HSE pressure systems

Heating

Adequate heating should be provided and the working temperature in each treatment room should be reasonable, (minimum 16°C). Heating appliances should be properly maintained in a safe condition. For example, regular portable appliance testing on electric heaters and annual gas safety checks on gas boilers. This will be your responsibility if you own the premises. If you rent your premises, it *may* be the building owner's responsibility, depending on the wording of your lease agreement.

Lighting

Each treatment room should be adequately lit by either natural or artificial lighting, or a combination of both. Windows should be sized to provide an acceptable level of natural light for the procedures to be undertaken. They should be screened to protect patient privacy and blinds should be easy to clean. Internal ledges to windows should be avoided to prevent build-up of dust and clutter. Sloping ledges discourage clutter and should be considered.

Health, welfare and safety

You must have appropriate arrangements in place for managing the health, welfare and safety of your patients and provide your service in a way that promotes their privacy and dignity. *Table 2* highlights the specific requirements, as defined in *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*.

Table 2 (Regulation 3: Welfare of users [extract])

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011	
Regulation	**Requirement**
3(a)	A provider must make proper provision for the health, welfare and safety of service users.
3(b)	Provide services in a manner which respects the privacy and dignity of service users;

Health and safety arrangements

Written risk assessments must be in place for all key risks in your service. You should also have a written health and safety policy.

The Health and Safety Executive (HSE) is responsible for enforcing health and safety law in healthcare premises in Great Britain. Healthcare Improvement Scotland has a memorandum of understanding with the HSE to report matters of evident concern. If we identify any significant and/or imminent risks to your patients during registration or our routine regulatory duties, we will immediately report these to the HSE.

While the HSE is the primary regulator for health and safety at work, you must be able to demonstrate to Healthcare Improvement Scotland how you maintain your premises and equipment, under Regulation 3(a) of *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*. For example, you should be able to provide evidence of:

- appropriate maintenance of portable electrical appliances
- routine fixed electrical wiring testing (known as an electrical installation condition report [EICR])
- annual gas safety check on gas boilers

- appropriate testing, servicing and calibration of specialist equipment (e.g. pressure vessels, lifts and lifting equipment, radiation equipment etc), and
- regular servicing and maintenance of standard equipment in line with manufacturers' recommendations.

Fire safety arrangements

The Scottish Fire and Rescue Service (SFRS) is responsible for enforcing fire safety in Scotland, under the *Fire (Scotland) Act 2005* and the *Fire Safety (Scotland) Regulations 2006.* As a provider, you must be able to demonstrate that you have made *proper provision for the health, welfare and safety of service users*. Therefore, you must provide a suitable fire risk assessment, demonstrate that you have acted on any recommendations made and have routine maintenance processes in place for all your fire equipment (alarms, extinguishers, emergency lighting).

Under this legislation, the 'Duty Holder' is responsible for fire safety. Depending on whether you own or lease your premises, the 'Duty Holder' may be you, your employer or the owner of the premises (landlord), or the occupier (person or business leasing the premises from the owner). Your lease/rental agreement should specify who the Duty Holder is.

Further advice on fire risk assessments is available at www.gov.uk and SFRS.

Privacy, dignity and security

Your premises should be safe and secure so that people using your service feel safe. Things to consider are secure door entry systems, staggered treatment appointment times, solid lockable treatment room doors and blinds on windows or frosted glass.

Managing accidents, incidents and adverse events

We expect you to keep a record of all accidents, incidents and adverse events that involve you, your employees or patients. This will help demonstrate how you managed them and enable you to identify any improvement action to be taken.

You are also legally required to report certain accidents, diseases and near misses to the Health and Safety Executive (HSE) under the *Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013*) (RIDDOR). Further information is available at www.hse.gov.uk/RIDDOR. It is your responsibility to familiarise yourself with what is required to be reported and make sure you have an appropriate system in place to do so.

Notifications

Once registered, you **must** formally 'notify' Healthcare Improvement Scotland of certain situations, within specified timescales. Notifications are made through the eForms portal. Examples of notifiable situations include:

- a serious injury or complication to a service user
- incidents reported to or investigated by the Police
- change of address of service or provider
- change of name of service or provider
- absence of a registered service manager
- change of name / appointment of new registered service manager

Please refer to the Notifications Guidance for further information about the types of incidents you must report, the timescales you must report them within and how to make a report.

Systems, processes and procedures

You must have appropriate systems, processes and procedures in place for the type of service you provide. *Table 3* highlights the specific requirements, as defined in *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*.

Table 3 (Regulation 3: Welfare of users [extract])

The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011	
Regulation	**Requirement**
3(d)(i)	A 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: (i) the prevention and control of infection; (ii) the decontamination of equipment; (iii) the management of clinical and other waste; (iv) the management of medication; and (v) the use of Class 3B or Class 4 laser and intense light source equipment.

You must have policies and procedures that describe *what* you do and *how* you do it. Your policies and procedures will not be deemed adequate if they do not describe what happens in your service or they describe what ***should*** be in place, rather than what actually ***is*** in place. In order to be adequate, your policies and procedures must:

- be clearly set out and easy to understand
- have a clear review process, with the implementation date and due date for review
- accurately reflect how your service operates
- comply with relevant legislation, and
- follow best practice guidance and Scottish standards where appropriate.

Guidance on writing policies is available in our example policy template. You can also research to find other examples. The types of policies and procedures you need will vary according to the type of service you provide. However, there are some basic key policies and procedures all services must have in place. For example:

- infection prevention and control
- management of medicines
- clinical governance
- safeguarding (vulnerable adults and children)
- complaints handling, and

- duty of candour.

Further guidance on the types of policies you need is available on our website.

The prevention and control of infection

As a healthcare provider, you must be able to demonstrate how you and your staff will adhere to Healthcare Improvement Scotland's Healthcare Associated Infection (HAI) Standards 2022. These specify the minimum level of performance for infection prevention and control practice in all healthcare settings. These standards are aligned with Health Protection Scotland's National Infection Prevention and Control Manual, which is Scotland's best practice guide to infection prevention and control practice.

Your infection prevention and control policy must set out (as a minimum) ***how*** you will implement and monitor the 10 standard infection control precautions (SICPs) described in the National Infection Prevention and Control Manual. If you employ staff, you should carry out regular infection prevention and control audits to demonstrate how you monitor compliance and identify improvements.

The decontamination of equipment

Health Protection Scotland's Compendium of Healthcare Associated Infection Guidance contains links to current national policy and guidance on decontamination and other related topics. It provides an overview of all up-to-date guidance from stakeholders/organisations and includes supporting materials such as literature reviews, tools and posters.

The management of clinical and other waste

You must have appropriate arrangements in place for the proper storage, collection and disposal of clinical and other waste generated by your service. This includes:

- establishing a contract with an appropriate specialist waste company for the removal and legally correct disposal of the waste you generate
- appropriate segregation of waste within your premises (for example separating clinical waste from domestic waste, disposing of sharps using approved sharps bins), and storage and disposal of different waste types using the correct European Waste Catalogue (EWC) code (e.g. botulinum toxin contaminated sharps are classified as a *cytostatic medicine* and must be correctly disposed of in a sharps box with the EWC 18-01-08 code regardless of its lid colour).

Safe and secure handling of medication

You must ensure compliance with legal requirements and current best practice recommendations for the safe, effective and secure use of medicines. Our Medicines Governance Audit Tool will assist you in assessing your compliance with legislation and best practice.

You must have secure storage at your premises for medicines, including a designated refrigerator approved for the storage of temperature-controlled medicines. You must monitor the operating temperature of the refrigerator and keep a written record to demonstrate that medicines are stored within the correct temperature parameters as required by the manufacturer. Records must be kept of corrective action where the temperature range falls outwith the safe storage range.

The use of Class 3B and 4 laser and intense pulsed light equipment

If Class 3B / Class 4 lasers or intense pulsed light (IPL) equipment are used in your service, you must be able to demonstrate a suitable environment for using this equipment. You must also have appropriate risk assessments and effective governance arrangements in place.

Further information about the key expectations can be found in the Medicines and Healthcare products Regulatory Agency's Lasers, intense light source systems and LEDs in medical, surgical, dental and aesthetic practices guidance - September 2015.

As a first step, you must appoint an external Laser Protection Advisor (LPA). The LPA should be certificated in the Medical and Aesthetic Sectors as a laser safety professional and registered on the Association of Laser Safety Professionals website.